The destabilising effects of patient choice: law, policy, politics and the paradox of complementary alternative medicine in the NHS

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Submitted in fufilment of the requirements of the

Degree of Doctor of Philosophy

on 5th April 2013

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Abstract

Despite the unproven effectiveness of many practices under the umbrella term 'complementary alternative medicine' (CAM) there is considerable public demand for, but only limited provision of, CAM within the English National Health Service (NHS). This thesis examines whether government support for patient treatment choice creates a bigger space for CAM within the NHS. It argues that policy-makers use choice both as policy initiative and as rhetorical device where the reference to choice ranges from liberal choice to consumer choice. At the same time treatment choice and personalised healthcare are politically justified by relying on the traditional NHS values of equity and universality and on the notion of patient responsibilisation. The different meanings claimed for choice in the political domain are mirrored by the perceptions of patient choice in tort law and in public law (including its European Union dimension). However, the legal analysis shows that English domestic law will not generally uphold the NHS patient's claim to a specific treatment.

The thesis suggests that private and public law litigation by patients to enforce their demands against a doctor or health authority not only functions as a dispute resolution mechanism but also exerts unsettling effects on healthcare institutions and practices. Although these effects are unlikely to be intended by the litigants they in turn support policy-makers' use of choice as a lever for change and reform. The thesis concludes that the government patient choice policy ought to be viewed as a strategy to destabilise and to encourage change within the NHS and its entrenched institutions and may have the unintended consequence of the emergence of a greater role for CAM. This finding coincides with the theme in government healthcare policy of patient responsibilisation also promoted by CAM's emphasis on self-care and self-management.

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Acknowledgements

No thesis is written in isolation and this one is no exception. There are many people to whom I owe a debt of gratitude for their part in bringing my thesis to fruition. In particular I would like to thank my supervisor Professor Richard Ashcroft for his guidance from the beginning of this journey that became my PhD and who challenged me to think about things in a different way. I am also most grateful to my supervisor Professor Kenneth Armstrong for guiding my research during the later stages of my PhD.

I am also thankful to Professor Rachael Mulheron who helped to shape my initial research efforts and to Professor Kate Malleson for her general advice and guidance during the course of the PhD. I also wish to acknowledge my appreciation for the helpful comments and information from numerous other people, in particular Dr. Catherine Needham, Dr. Amy Ford and Professor Edzard Ernst.

Finally, I would also like to thank my family and friends who have supported me throughout when I had little time for them.

Introduction

Demand for complementary alternative medicine in England

Complementary alternative medicine (CAM) in the UK bridges private and publicly funded healthcare settings. The extent of the use of CAM is not routinely measured, and any figures available are based on data from surveys which are generally out of date.[1] There are some indications of the extent of access to CAM services. According to a survey of the UK in 2001, 10% of adults saw a complementary therapist in any twelve-month period, with more than half using at least one of five specific therapies.[2] An earlier survey, conducted in England in 1998, found that, if remedies purchased over the counter are included, the proportion of adults having used CAM in the past twelve months is estimated to be almost 12%, rising to almost 50% for lifetime use.[3] Extrapolated data from a BBC survey on consumer spending on CAM in the UK led to an estimate of £1.5 billion in 1999,[4] probably including over-the-counter sales.

Complementary alternative therapy provision in the NHS

It has been estimated that just 10% of the overall contacts with CAM practitioners in England are publicly funded through the National Health Service (NHS).[5] From a survey conducted in 2001 it was estimated that almost half the general practices in England were providing some access to CAM therapies, although the treatment was

[1] S Boyle, 'United Kingdom (England): Health System Review' (2011) Health System in Transition 1, 341; House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000) 1.14–1.21.
[2] KJ Thomas and P Coleman, 'Use of Complementary or Alternative Medicine in a General Population in Great Britain. Results from the National Omnibus' (2004) 26 Journal of Public Health 152, 153 referring to acupuncture, homeopathy, chiropractic, osteopathy or herbal medicine.
[3] KJ Thomas and others, 'Use and Expenditure on Complementary Medicine in England: A Population Based Survey' (2001) Complementary Therapies in Medicine 2, 2.
[4] E Ernst and A White, 'The BBC Survey of Complementary Medicine Use in the UK' [2000] Complementary Therapies in Medicine 32, 33.
[5] KJ Thomas and others, 'Use and Expenditure on Complementary Medicine in England: A Population Based Survey' (2001) Complementary Therapies in Medicine 2, 6.

not necessarily funded by the NHS.[6] According to the Smallwood Report in 2004, over 40% of Primary Care Trusts (PCTs) offered some form of CAM, with London PCTs providing the most access to these.[7] Access to CAM as part of primary care is also possible with specialist CAM centres contracted with the NHS.[8] Access to CAM is also provided in NHS hospitals by NHS-employed healthcare professionals as part of an integrated approach to cancer care and also part of end of life care,[9] and in the three homeopathic hospitals in England including the Royal London Hospital for Integrated Medicine.[10]

Patient treatment choice in the NHS: a contradiction?

Despite the patchy data available it is apparent that, despite the cost-disincentives, there is considerable public demand for CAM but only very limited provision within the NHS. Public demand for CAM may be due, amongst other things, to the discontent with biomedicine because of the side-effects of drugs and their lack of effectiveness in many chronic conditions, the belief that CAM is less invasive and more natural, the greater involvement by the patient in the treatment, and the different relationship between CAM practitioner and client.[11] At the same time, the widespread use of CAM, and CAM itself, are being challenged by its opponents within and outside the biomedical profession who stress the unproven effectiveness

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[6] KJ Thomas and others, 'Trends in Access to Complementary or Alternative Medicines via Primary Care in England: 1995–2001 Results from a Follow-up National Survey' (2003) 20 Family Practice 575, 575.

[7] C Smallwood, 'The Role of Complementary and Alternative Medicine in the NHS: An Investigation into the Potential Contribution of Mainstream Complementary Therapies to Healthcare in the UK', FreshMinds, London 2005) 126 <www.getwelluk.com/uploadedFiles/Publications/SmallwoodReport.pdf> accessed 15 November 2010.

[8] S Boyle, 'United Kingdom (England): Health System Review' (2011) Health System in Transition 1, 339 giving as an example the Centre for Integrated Medicine in Winchester, but treatment funded by the NHS is only available if the patient's general practitioner is willing to submit a funding application to her PCT and the PCT is willing to agree to the request.

[9] S Boyle, 'United Kingdom (England): Health System Review' (2011) Health System in Transition 1, 340.

[10] C Zollman and A Vickers, 'ABC of Complementary Medicine: Complementary Medicine in Conventional Practice' (1999) 319 BMJ 901, 901.

[11] S Cant and U Sharma, *A New Medical Pluralism* (UCL Press 1999) 46–47.

and the potential dangers of these treatments.[12] However, the restricted provision within the NHS, which is unlikely to have increased in the past few years since the surveys were carried out,[13] seems to contradict the patient choice and patient treatment choice policies of the current coalition and the previous New Labour governments.

The concept of patient choice

The policy of patient choice of treatment by policy-makers seems to suggest that patients are given a right to a specific treatment of their choosing and that this right might extend to include CAM. This is also a conclusion that can be drawn from the response by the current coalition government to the recommendations regarding the use of homeopathy in the NHS by the House of Commons Science and Technology Committee.[14] Patient choice appeared to trump the lack of evidence base of homeopathy, with decisions on treatment to be made at the micro- and meso-levels between doctor, PCT and patient.

The dictionary definition of choice as 'an act of choosing between two or more possibilities'[15] is not of much assistance in attempting to define the policy of patient (treatment) choice at the macro-level or at the micro- and meso-levels of the healthcare system. Choice carries different meanings in different contexts. Thus, patient choice can be linked with the concept of the right or freedom to choose as a liberal value also circumscribed by the concept of autonomy. Choice can also be linked with the idea of the consumer in the market exchanging money for the desired

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[12] I Evans and others, *Testing Treatments* (2nd edn, Pinter & Martin 2011); S Singh and E Ernst, *Trick or Treatment: Alternative Medicine on Trial* (Bantam Press 2008); R Shapiro, *Suckers: How Alternative Medicine Makes Fools of Us All* (Vintage 2009); see also D Colquhoun, *'The Quack'* page at <www.ucl.ac.uk/pharmacology/dc-bits/quack-01-06-07.html> accessed 10 October 2010.

[13] In part due to the recommendations of the House of Commons Science and Technology Committee that the use of homeopathy should be withdrawn from the NHS, see House of Commons, *Report of the Science and Technology Committee*, *Evidence Check 2: Homeopathy* (HMSO 2010); and in part due to the low-priority treatments policies of primary care trusts classifying CAM as treatments of low priority.

[14] Department of Health, *Government Response to the Science and Technology Committee Report, 'Evidence Check 2: Homeopathy'* (HMSO 2010).

[15] At http://www.oxforddictionaries.com/definition/english/choice accessed 1 September 2012.

goods or services, relevant in the context of healthcare mimicking market principles, in private healthcare and in the context of treatment across borders in the European Union. Lastly, patient choice at the macro-level may be understood as referring to liberal choice or to consumer choice, but in this context it may also be used by policy-makers as a policy mechanism with specific political objectives.[16] The argument about patient treatment choice of CAM overlaps these different interpretations of choice employed at the various levels of healthcare decision-making covered in the chapters.

The concept of destabilisation

Destabilisation is a theme linking patient choice as a policy mechanism, discussed in chapter 1, with the possible effects of patient choice litigation in tort law, covered in chapters 2 and 3, and in public law, covered in chapters 4 and 5. According to the Oxford English Dictionary definition, destabilisation denotes '[to] upset the stability of; cause unrest in'[17] a system. The notion of destabilisation is borrowed from Sabel and Simon's concept of 'destabilisation rights' in public law as 'claims to unsettle and open up public institutions that have chronically failed to meet their obligations and that are substantially insulated from the normal processes of political accountability'.[18] Rather than referring to destabilisation *rights*, destabilisation is described as the possible ramifications of threatened or actual litigation by patients who have been refused their (treatment) choice on the status quo of the healthcare system, effects which go beyond the immediate parties to the (intended) action in tort law and in public law. In the context of the healthcare system at the macro-level, destabilisation is expressed as the intended effect of patient choice policies

[16] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 251.
[17] <http://www.oxforddictionaries.com/definition/english/destabilize> accessed 1 September 2012.
[18] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1020.

encouraging reform of the institutional architecture of the NHS, of the incumbent institutions.[19]

The definition of complementary alternative medicine

Complementary alternative medicine, or CAM, is a term describing a vast number of treatment modalities. The diversity of these therapies makes them difficult to categorise as a group, yet they are often collectively referred to as 'complementary', 'alternative', 'integrative', 'unorthodox', 'unconventional', 'unproven', 'natural', 'traditional' and 'holistic' medicine, and are contrasted with 'conventional', 'mainstream', 'allopathic', 'orthodox', 'conventional' and 'scientific' medicine.[20]

The definition of CAM by the House of Lords Committee on Science and Technology as a 'diverse group of health-related therapies and disciplines which are not considered to be a part of mainstream medical care'[21] has been adopted in this thesis. While this definition at once delineates CAM from orthodox medicine, it does not exclude practice of CAM by the medical profession, nor does it exclude referral of patients by orthodox medical practitioners to CAM practitioners. I have also adopted the Committee's classification of the different CAM therapies into the following three groups[22]:

- Group 1 includes the principal disciplines, which also claim to have an individual diagnostic approach, namely osteopathy and chiropractic, acupuncture, herbal medicine and homeopathy.
- Group 2 contains therapies which are mainly complementary to conventional medicine and do not purport to embrace diagnostic skills.

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[19] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250; S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics Policy and Political Reactions to European Union Healthcare Services Law' (2011) Journal of European Public Policy 220, 221.

[20] V Kotsirilos, 'Complementary and Alternative Medicine. Part 1– What Does It All Mean?' (2005) Aust Fam Physician 595, 595.

[21] House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000) 1.8.

[22] ibid 2.1.

They include aromatherapy, the Alexander Technique, body work therapies including massage, counselling and hypnotherapy.

- Group 3 includes therapies claiming to offer diagnostic information as well as treatment. These therapies, in general, favour a philosophical approach and are indifferent to the scientific principles of conventional medicine. They include Ayurvedic medicine and Traditional Chinese medicine, and also as crystal therapy, iridology, and kinesiology.

Since the group 1 treatments are the ones used most widely by the public,[23] the discussion of CAM in the thesis will concentrate on these treatments unless otherwise stated. Similarly to all CAM modalities, the treatments in group 1 are diverse, with very different theories for their mode of action.[24] However, the group 1 treatments also have features in common. They have the greatest claim to professional organisation by their practitioners.[25] Practitioners of osteopathy and chiropractic are regulated in their professional activity and education by Acts of Parliament.[26] Professional organisations for medical practitioners who practise osteopathy, acupuncture or homeopathy are in existence.[27] Group 1 is also the group of treatments which is most likely to have been made available by the NHS.[28] Although all CAM therapies are based on theories about their modes of action that are not congruent with current scientific knowledge, osteopathy, chiropractic, acupuncture and herbalism have scientifically established efficacy in the treatment

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[23] K Thomas and P Coleman, 'Use of Complementary or Alternative Medicine in a General Population in Great Britain. Results from the National Omnibus' (2004) 26 Journal of Public Health 152, 153.
[24] E Ernst and others, *The Desktop Guide to Complementary and Alternative Medicine: An Evidence-Based Approach* (2nd edn, Mosby 2006) 292–344.
[25] S Boyle, 'United Kingdom (England): Health System Review' (2011) Health System in Transition 1, 338.
[26] Osteopaths Act 1993 and Chiropractors Act 1994.
[27] British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 41 referring to the Faculty of Homeopathy, the British Osteopathy Association and the British Medical Acupuncture Society.[27]
[28] K Thomas and others, 'Trends in Access to Complementary or Alternative Medicines via Primary Care in England: 1995–2001 Results from a Follow-up National Survey' (2003) 20 Family Practice 575, 575-576.

of a limited number of ailments.[29] Some of the CAM modalities in group 1 have also been evaluated by the National Institute for Clinical Excellence when developing clinical guidance. [30]

Methodology and purpose and aim of research

The methodology employed in this thesis is socio-legal in its widest sense. The meaning of socio-legal is taken to extend beyond its definition as synonymous with sociology of law or critical legal studies, and is not restricted to relating to empirically based studies or applied research.[31] Rather, socio-legal is defined as an approach evaluating the impact of law in society and the relationship between law and other disciplines. Thus, 'the "socio" in socio-legal studies means … an interface with a context within which law exists, be that a sociological, historical, economic, geographical or other context'.[32] It therefore encompasses historical and contemporary analyses of the social, economic and political factors involved in the development of law, as well as analyses of law and its relationship to society and the State.[33]

Most academic writing on the issue of patient choice restricts the discussion on either a private law or a public law standpoint with the writing on the European Union (EU) dimension generally adding a further, separate perspective. In private law, much of the literature on patient choice tends to be doctrinal focussing on the issue of patient autonomy or patient rights under battery, or the issue of information

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[29] House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000) 2.6; see generally E Ernst and others, *The Desktop Guide to Complementary and Alternative Medicine: An Evidence-Based Approach* (2nd edn, Mosby 2006).
[30] eg clinical guidelines on treatment of low back pain <http://guidance.nice.org.uk/CG88/Guidance/pdf/English> accessed 30 January 2010; E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350–56 discussing the evaluation of 65 guidelines on the NICE website in August 2009 .
[31] M Partington, 'Implementing the Socio-Legal: Developments in Socio-Legal Scholarship and the Curriculum' in G Wilson (ed), *Frontiers of Legal Scholarship* (John Wiley & Sons 1995) 93.
[32] S Wheeler and P Thomas, 'Socio-Legal Studies' in D Hayton (ed), *Law's Future(s)* (Hart 2000) 271.
[33] M Partington, 'Implementing the Socio-Legal: Developments in Socio-Legal Scholarship and the Curriculum' in G Wilson (ed), *Frontiers of Legal Scholarship* (John Wiley & Sons 1995) 93 referring to the definition by the Economic and Social Research Council (ESRC) in ESRC, *Review of Socio-Legal Studies: Final Report* (1994) (ESRC 1994).

disclosure under negligence. The discussion largely turns on the fallacy of the judicial interpretation of autonomy and on whether tort law is a suitable vehicle to enforce patients' rights. Choice is debated as an expression of patient preference to select amongst options deemed appropriate by the doctor rather than a question of rights. Some attention is paid to professional guidance as more receptive to the notion of patient rights than the law. A few writers suggest that this understanding of professional guidance may have some impact on future litigation, an argument which is followed up and expanded on in this thesis. In public law, the issue of patient rights is generally discussed as a question of resource allocation with the tension between individualism and universality. The doctrinal legal analysis, to a large extent, concentrates on judicial review applications and the perceived role of the court in the assessment of the lawfulness, rather than the merits of the decision of the health authorities. In both private and domestic public law there is little discussion of the influences of litigation on healthcare policy and stakeholders. In contrast, much of academic writing on patient choice in EU law concerns itself with more than doctrinal legal analysis and considers the destabilising effects of the decisions of the European Court of Justice (ECJ)[34] on the healthcare systems of EU Member States. These in turn are discussed as producing responses from stakeholders in the member States influencing policies at EU level.

Rather than following the current discussion of patient choice in either private or public or EU law, this thesis situates choice in law at the micro-, meso- and macro-levels of the English NHS and the UK's membership of the European Union, and interacts with the perspective of other disciplines including ethics, history, policy and political discourse, and to a minor extent, empirical health science. While such an interdisciplinary approach has the benefit of considering English healthcare law from different angles, it has the drawback that it is difficult to do the various disciplines justice regarding the methodologies and practices common in these

[34] Since the coming into effect of the Lisbon Treaty, the ECJ is referred to as the 'Court of Justice'. As the cases discussed in this thesis were already concluded, the term ECJ will be used throughout for ease of reading.

disciplines. It further has the drawback that detail in the themes addressed had to be compressed or excluded altogether.

The thesis refrains from adopting a pure black letter law approach, as this would not have been effective in analysing the key issues of this research.[35] The thesis goes beyond the analysis and critique of legal principles and broadens the scope of legal research, making it possible to explore its broader context to enable the examination of government policy arguments. Rather than focussing on doctrinal legal research, it exposes the interconnectedness of law and government policy and their impact on each other in the healthcare setting, determined by ethical, social and political considerations. The recourse to historical discourse is intended to aid the understanding of the development of policies regarding non-mainstream healthcare such as CAM in the NHS.

A pure doctrinal analysis of patient treatment choice leads to the conclusion that patients do not generally have a right to demand a specific treatment. A different approach was therefore necessary to understand what appeared to be a paradox, namely government support for treatment choice, and even more so, the support for patient choice of CAM. This required answers to a number of questions regarding the interpretation of choice at the level of government such as what choice means at the policy level, whether choice is used as a rhetorical device or as a policy initiative. It also was necessary to consider an explanation for treatment choice of CAM in the context of the NHS because of the unproven effectiveness of many CAM practices. Government policy papers suggested a link between choice and other policy concepts such as personalisation and responsibilisation and their justification in terms of the settlement values of the NHS, a link also explored by Veitch[36]. The discussion of these concepts, however, leaves the lack of enforceability of treatment choice in English law unexplained.

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[35] A Bradney, 'Law as a Parasitic Discipline' (1998) 25 J Law and Society 71, 78.
[36] K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313.

ECJ mobility case law suggests that EU citizens have a right to obtain specific healthcare across borders without prior authorisation at the cost of their national healthcare systems. The exercise of this right encourages instability in the national healthcare systems and healthcare institutions leading to responses from governments and other stakeholders not only domestically, but also with bottom-up effects on EU institutions and regulations.[37] Using the analogy of ECJ patient mobility litigation, similar effects of domestic private and public law litigation on NHS institutions and practices were possible. Writers on EU law and policy such as Greer and Rauscher embraced the logic of destabilisation rights[38] described by Sabel and Simon in the specific context of public law litigation in the United States but then expanded to include private law litigation.[39] Miola amongst others has drawn attention to the symbiotic relationship between medical, private law and medical ethics in England.[40] This thesis has adopted and expanded on this argument regarding patient treatment choice, analysing the effect of private law litigation on professional guidance as leading to a change in medical practice. In the public law area, little debate has been forthcoming in academic literature concerning the effects of judicial review of individual funding requests on healthcare institutions and practices. However, Platt and others, for example, discuss the positive effects of judicial review on public administration in local government,[41] which has a possible resonance for the decision-making by health authorities. While not using the language of destabilisation, the authors refer to public law litigation acting 'as a lever for change'.[42]

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[37] W Palm and I A Glinos, 'Enabling Patient Mobility in the EU; Between Free Movement and Coordination' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010)

[38] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220.

[39] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016

[40] J Miola, *Medical Ethics and Medical Law, A Symbiotic Relationship* (OUP 2007).

[41] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' (2010) J Public Adm Res Theory (suppl 2): i243.

[42] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' (2010) J Public Adm Res Theory (suppl 2): i243, i243.

The impact of private and public law 'choice' litigation on the NHS and its institutions can be contrasted with the choice and its interpretation at the level of government. Choice at the macro-level can be analysed as rhetoric or a policy initiative suggesting liberal or consumer choice, but also as a different facet of change and destabilisation. Clarke and others, for example, see government employ choice as a policy mechanism destabilising the institutional architecture of the NHS.[43] A similar argument is used by Schelkle and others in their discussion on welfare reform in Europe regarding consumer choice as a proactive, government-led reform strategy.[44] The analysis then suggests that at the level of the individual, patient choice of CAM becomes part of this government strategy and the possible beneficiary of choice-led reform.

The research methods utilised in this thesis were based on a theoretical, literature-based approach. Due to the interdisciplinary approach used, the scope of research materials consulted is more extensive than would have been required by a focus on a pure black letter law framework. The legal materials include English and EU as well as some Canadian and US case law, English statute law and international legal material and legal academic commentary. In addition, materials included also embrace policy documents, White Papers, Select Committee documents, Department of Health documents, ethical guidance by professional bodies and guidance by National Health Service bodies, patient survey reports and academic commentary from a variety of disciplines. There was also some use of internet sources.

The aim of the thesis is to make a distinctive contribution to the literature by adding to the debate on the meaning and effects of patient treatment choice in the context of CAM within the English NHS and in English private and public law. Specifically, the research addresses the question whether macro-level patient treatment choice of

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[43] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

[44] W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 1 <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012

CAM is a paradox not simply because CAM is not part of the dominant biomedical paradigm but because at the micro- and meso-levels of the healthcare system experience shows that patients' treatment demands are often unsuccessful being subject to implicit and explicit rationing decisions.

The purpose of the research is to explore whether the possible destabilisation of the patient choice policy at the macro-level and of patient choice litigation at the meso- and micro-levels in the NHS has the potential of reconfiguring a space for CAM in the NHS. To this end, the relationship between a macro-level policy of patient choice and the traditional values of the NHS, and the different interpretations of patient choice in private and public law and in the patient mobility jurisprudence of the European Court of Justice are examined. The research pulls together three themes: firstly, the history and politics of patients' choice of CAM in the English NHS; secondly, the legal and ethical aspects of patient choice in tort law; and thirdly, the legal and policy aspects of patient choice in public law as affected by the Treaty on the Functioning of the European Union (TFEU).

Exclusions

Much of the literature on CAM deals with the problem of its unproven effectiveness and the potential safety concerns,[45] or the question of the regulation of CAM practitioners.[46] Whilst not ignoring this literature, the thesis considers complementary medicine from a different perspective, namely the vantage point of patient choice at the macro-, meso- and micro-levels within the English NHS. It is

[45] E Ernst and others, *The Desktop Guide to Complementary and Alternative Medicine: An Evidence-Based Approach* (2nd edn, Mosby 2006); I Evans and others, *Testing Treatments* (2nd edn, Pinter & Martin 2011); S Singh and E Ernst, *Trick or Treatment: Alternative Medicine on Trial* (Bantam Press 2008); R Shapiro, *Suckers: How Alternative Medicine Makes Fools of Us All* (Vintage 2009); KM Boozang, 'Western Medicine Opens the Door to Alternative Medicine' (1998) 24 Am J L & Med 185.
[46] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996); MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998); SY Mills, 'Regulation in Complementary and Alternative Medicine' (2001) 322 BMJ 158; P Tovey and others (eds), *The Mainstreaming of Complementary and Alternative Medicine: Studies in Social Context* (Routledge 2003); S Welsh and others, 'Moving Forward? Complementary and Alternative Practitioners Seeking Self-Regulation' (2004) Sociology of Health & Illness 216.

concerned with CAM provision at the primary (rather than secondary or tertiary) care level for patients with long-term chronic illness, which is where most CAM is used. Although much of the expenditure on CAM is on remedies purchased over the counter,[47] the thesis is not concerned with self-help remedies but rather with CAM administered by doctors or CAM practitioners. Lastly, the thesis only includes the English NHS rather than the NHS in Wales, Scotland and Northern Ireland. This is not only because of the different values and policies of the healthcare services in the different parts of the UK,[48] but also because the legal analysis is restricted to English law.

The research for this thesis only covers the period up to 1st March 2013. Any developments or changes in the law or the NHS after that date are not included.

Outline of chapters

The thesis is set out in five chapters which are linked by the different interpretations of patient choice.

Chapter 1 discusses patient choice within the National Health Service (NHS) in England from a historical and political perspective. It reflects on the space for CAM in a health service based on a biomedical healthcare paradigm, where there is public demand for such treatment. It explores the possible contradictions of a macro-level patient treatment choice in a publicly funded health service which is founded on the values of comprehensiveness, equity and universality.[49] Although patient choice has been attacked as a proxy for competition and marketisation and because of its

[47] K Thomas and P Coleman, 'Use of Complementary or Alternative Medicine in a General Population in Great Britain. Results from the National Omnibus' (2004) 26 Journal of Public Health 152.
[48] S L Greer and D Rowland, 'Introduction: Why Discuss Values in Health? Why Now?' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 11.
[49] See generally C Webster, *The National Health Service: A Political History* (2nd edn, OUP 2002); D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995).

inequitable effects[50] the chapter demonstrates that policy-makers of different political persuasions have adopted policies such as personalised healthcare and personal health budgets while being able to rely on the competing interpretations of the settlement values of the NHS for justification.[51] It is argued that, rather than viewing patient choice exclusively as a strategy for cost containment and marketisation these policies may be a mechanism concealing other political intentions. Policy-makers may be using patient (treatment) choice as a mechanism to destabilise the institutional architecture of the NHS and encourage reform.[52] The chapter concludes that this destabilisation may have the effect of reconfiguring the space for CAM in the NHS, helping to lower costs while at the same time encouraging self-care and self-management, thus reducing dependency on the NHS. Despite these macro-level policy arguments, in practice healthcare decisions are made at the micro- and meso-levels where patients' access to CAM may be compromised.

Chapter 2 links the concept of patient choice with the discussion of choice in its liberal or libertarian sense as a right to choose. Policy documents subject the right to treatment choice to the condition that treatment should be clinically 'appropriate'. The clinical appropriateness of a treatment is a decision reached at the micro-level, between the general practitioner and the patient. With chronic conditions, where patients are often experts about their symptoms and their responses to treatment, the decision may well be that complementary alternative therapy, amongst the various therapeutic options, is one of the appropriate treatments.

Where there is no conflict between doctor and patient, the patient will receive her preferred treatment. However, where there is conflict and medical law becomes involved, the question is whether the patient's right prevails. It becomes a question

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[50] See eg A Pollock, *NHS plc: The Privatisation of Our Healthcare* (Verso 2005).
[51] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research 1999) 7–15; R Klein, 'Values Talk in the (English) NHS' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 22–23.
[52] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

of how the courts interpret patient autonomy.[53] Patient autonomy is the concept employed by the courts in cases where the patient chooses to refuse *or* demand a specific treatment. In refusal of treatment cases, conceptually based on the tort of battery and the lack of consent by the patient to bodily interference, the judicial conception of autonomy has tended towards an interpretation in terms of rights, the patient's right to self-determination. This rights discourse might then be taken to imply a right to a specific treatment based on the common law[54] and under Article 8 ECHR, the infringement of the right to respect for one's private and family life.

The judicial conception of autonomy is, however, not consistent, not even in cases of lack of consent to treatment. It is demonstrated that the liberal notion of autonomy cannot be relied on as a right to a specific treatment. It cannot compel a doctor to act against her clinical judgment to provide a treatment that she regards as contrary to the patient's best interests,[55] whether such treatment is orthodox or CAM treatment. A doctor can legitimately decide that a treatment is not clinically indicated and need not be made available. It is argued, however, that litigation by patients, while not achieving the desired objective of acknowledging a right to choose, may have effects beyond the immediate parties to the action.[56] It is suggested that tort litigation may have a destabilising effect on healthcare practices and regulations. It leads and has led to a debate on patients' rights and a change in the attitude of the medical profession as represented by the guidance by the General Medical Council (GMC).[57] To that extent at least, it may explain why general practitioners are generally more open to the demand for CAM by patients with long-term chronic illnesses.

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[53] M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397;
J Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 Health Care Analysis 235.

[54] *R (Burke) v General Medical Council* [2004] EWHC 1879 (Admin).

[55] *Re J* (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15 (CA) 26; see also H Biggs, '"Taking Account of the Views of the Patient", but only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 234.

[56] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1057–58.

[57] General Medical Council, *Good Medical Practice* (GMC 2006); General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008); see also J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106.

Chapter 3 continues the theme of choice in the context of a patient's right to information about the different treatments available from the doctor. The question discussed in this chapter is the right of the patient to be informed about a proposed treatment and its alternatives, which may or may not include complementary alternative treatments, in order to arrive at an informed choice, an issue that is also sometimes referred to as 'informed consent'.

It is argued that English law in the area of information disclosure appears to have little concern for a patient's interest in information to arrive at an autonomous treatment choice.[58] On the one hand, the English judiciary has taken a minimalist interpretation of the information requirements necessary for real consent, ruling out medical trespass as long as the patient has been informed in broad terms about the treatment.[59] On the other hand, using the law of negligence involves a concern with the duty by the doctor to inform the patient, rather than the right of the patient to the information.[60] At the same time, the assessment by the courts of the adequacy of the information according to some version of the professional standard, together with the difficulty of proving causation, means that patients will rarely be successful in a claim for non-disclosure in negligence.[61] Whether in this legal setting a doctor is under a duty to divulge information about alternative treatment options such as CAM as outside the medical paradigm adds a further layer to the debate.

Patients have rarely been successful in informed consent claims because of the definitional limitations of both torts. It is argued, following Sabel and Simon, that the common law operates, however, not only as a system of dispute resolution but that informed consent litigation has wider ramifications on healthcare practices

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[58] See generally E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006).
[59] *Chatterton v Gerson* [1981] All ER 257; M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 172.
[60] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed) *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 275; A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 193.
[61] M Jones, 'Informed Consent and other Fairy Stories' 7 (1999) Med L Rev 103, 123.

generally.[62] Litigation, even if unsuccessful, may have the effect of destabilising the status quo, leading to a change in medical practices – evidenced by the frequent revisions to professional guidance on informed consent by the GMC.[63] The requirements in the GMC guidance are much higher than the minimal disclosure standards of the law[64] and may suggest the need to discuss CAM options with patients affected by long-term chronic conditions.

Chapter 4 connects with the discussion of the original settlement values in chapter 1. It places patient treatment choice in the context of the financial constraints of health authorities, at present PCTs and in future Clinical Commissioning Groups (CCGs), charged with making resource allocation decisions from their fixed yearly budgets.[65] Restricted finances have meant that some treatments, such as complementary alternative therapy, are not routinely available because they have been placed on a list of so-called 'low-priority' treatments.[66] Patients can make an individual funding request to their PCTs for such a treatment on the basis of exceptional circumstances, if supported by their GP. Where the request is refused, the patient may look to the courts for judicial review of the decision. The role of the court is to oversee the legitimacy, procedural propriety and reasonableness of the decision, rather than assessing the merits of the patient's claim.[67] In reaching its decision the court will review and rule on the appropriateness of the exceptionality criteria applied by the PCT.

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[62] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1057–58.

[63] General Medical Council, *Good Medical Practice* (GMC 2001); General Medical Council, *Good Medical Practice* (GMC 2006); General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998); General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008).

[64] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 286.

[65] National Health Service Act 2006 s 230; see also Health and Social Care Act 2012, s 223I with regard to CCGs.

[66] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA); see also C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 307.

[67] *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374, 410; see generally C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005); K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007).

In this chapter, I suggest that the exceptionality criteria emerging from case law are often ambiguous, leading to uncertainty for patients and health authorities.[68] To avoid the risk of litigation health authorities need to consider and weigh all relevant factors in the determination of the patient's exceptional circumstances, including an assessment of the effectiveness and cost effectiveness of the requested low-priority treatment. The assessment of the effectiveness of CAM modalities with their lack of scientific validation will be an added difficulty.

I will argue that the ambiguity of the exceptionality criteria emerging from case law not only has the potential of increasing the threat of litigation by patients but is also likely to have a destabilising impact on health authorities.[69] Despite the difficulty for patients to succeed in judicial review litigation, the threat of litigation may encourage PCTs to concede funding requests to avoid costly and time-consuming court proceedings and reduce the risk of further claims by patients.[70] Public law litigation has, however, still wider ramifications beyond the parties before the court. It may have consequences for the entire health care system. It changes the status quo, leading to public engagement, deliberation and negotiation, with effects on other institutions and practices.[71] In view of the personalised healthcare agenda and personal healthcare budgets it may lead to a changed space for CAM within the NHS. This softening approach towards CAM needs to be seen in the light of government policies, such as the 'responsibilisation' of the patient and the need for containment of healthcare costs, and of the impact of the patient mobility case law of the European Court of Justice.

Chapter 5 discusses the right of patients to receive healthcare in another EU Member State, and to be reimbursed by their healthcare system, a right which has been established in a series of judgments of the European Court of Justice (ECJ)

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[68] See generally A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1.
[69] See generally L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' (2010) J Public Adm Res Theory (suppl 2): i243.
[70] J Maybin and R Klein, *Thinking about Rationing* (King's Fund 2012) 25.
[71] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1055.

despite the fact that the EU has no formal competence to regulate national healthcare.[72] Cross-border healthcare has been interpreted by the ECJ as being an economic service,[73] which also applies to the NHS[74] with the patient either paying for the services in the 'host' Member State upfront or with the services being paid for by the 'home' Member State direct. Prior authorisation in case of hospital treatment has to be based on objective, non-discriminatory criteria, whereas for non-hospital care such as CAM, prior authorisation was found to constitute a barrier to the freedom to provide services.[75]

The chapter suggests that, despite the paucity of cases which have been referred to the ECJ, litigation by patients claiming treatment rights across borders has had the effect of destabilising national healthcare systems, with repercussions far beyond the number of patients who exercised these rights.[76] The legal uncertainty, due to the risk of patients obtaining treatment abroad to which they were not entitled in their home state, set in motion a restabilisation process which prompted political activity by the UK government and the NHS, leading to the drafting and adoption of the EU Directive on cross-border healthcare.[77] The Directive is expected to end legal uncertainty about the care patients can receive abroad, while allowing the NHS to maintain control over patients' entitlements.[78] The thesis argues, however, that legal instability may persist as the Directive appears to perpetuate some of the issues

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[72] Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931, para 17; Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 44.
[73] Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931, para 17.
[74] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 146.
[75] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 44.
[76] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220, 222.
[77] The Directive on the application of patients' rights in cross-border healthcare TC2-COD (2008)0142.
[78] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

which caused the destabilising effects of ECJ case law on the NHS. One of these issues concerns the undefined health benefit basket of the NHS which does not exclude altogether treatments such as CAM. There is therefore scope for patients' claims for reimbursement from PCTs for the costs of cross-border CAM to expand, indirectly, the availability of CAM from the NHS.

Chapter 1
The history, politics and policy of patient choice at the macro-level: Interpreting patient access to CAM in the English NHS

1.1. Introduction

This chapter considers the development of patient choice and patient treatment choice in the National Health Service (NHS) in England[79] from historical and political perspectives and reflects on the space for complementary alternative medicine (CAM) within the NHS as part of the government policy of choice. As such it discusses the original settlement of the NHS in 1948 which made no reference to patient choice. At the same time it describes the NHS as based on a predominantly biomedical healthcare system dominated by a powerful medical profession, which has largely excluded CAM. From 1989 a new political discourse led to institutional changes in the NHS, representing a break with the past. A quasi-market model of the NHS emerged where managers rather than doctors are in control of finances, the power of the medical profession is considerably curtailed, and choice, efficiency and competition are championed. There is an obvious tension between what has been termed the 'church' of the NHS,[80] with its socialist values and aspirations, and the new, business-like 'NHS plc'.[81]

The chapter demonstrates that although patient choice has been attacked as being a proxy for competition, efficiency, marketisation and possible privatisation policies, and also for its inequity-inducing effects, there is continuity between the old and the new NHS. This is because policy-makers of different political persuasions can

[79] Discussion of the NHS in Wales, Scotland and Northern Ireland is excluded as these healthcare systems have taken a divergent path due to the devolution settlement, see SL Greer and D Rowland, 'Introduction: Why Discuss Values in Health? Why Now?' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007).
[80] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 280–83.
[81] A Pollock, *NHS plc: The Privatisation of Our Healthcare* (Verso 2005).

justify patient choice by relying on the competing interpretations of the original values of the NHS. It is argued that rather than regarding patient choice exclusively as a strategy to encourage containment of cost, as well as marketisation and privatisation of the NHS, it may be open to different interpretations.[82] It is suggested that governmental choice and treatment choice policies may hide other political intentions, namely that policy-makers may be using the patient choice agenda as a mechanism to destabilise the institutional architecture of the NHS and encourage reform[83] while at the same time demonstrating a commitment to the values of the NHS and to fiscal prudence.[84] CAM may become the unintended beneficiary of this strategy with the treatment choice policy leading to the opening of a greater space for CAM in the NHS.

The chapter first discusses the core values and aspirations of the NHS when it was first founded in 1948, the 'NHS church', i.e. the values of comprehensiveness, universality, equity and free healthcare. It then proceeds to examine choice and efficiency, two of the new policies in the transformed NHS –'NHS plc'. Interwoven in this discussion is a short outline of the history and development of CAM within the NHS.

1.2. The NHS as a secular church: The traditional values of the English NHS

The National Health Service Act 1946 is silent on the core values underlying the NHS, stating that the aim of the NHS is 'to promote the establishment in England and Wales of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and Wales and the prevention,

[82] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.
[83] ibid; see also W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 1 <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012.
[84] See eg C Needham, 'Interpreting Personalisation in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204, 213.

diagnosis and treatment of illness'.[85] The solidaristic principles underlying the NHS can be gleaned from the wartime Beveridge Report. Referring to the funding of the healthcare system at the time in terms of a compulsory health insurance, it is an exhortation of 'men stand[ing] together with their fellows' and speaks of a 'pooling of risks'.[86] For Aneurin Bevan, the architect of the NHS and also its first Health Minister, making the patient's access to care independent of income within a state-funded health service would prevent the anxieties caused by illness and economic necessity. A 'free health service was pure socialism…opposed to the hedonism of capitalist society'[87] leading to a society becoming 'more wholesome, more serene and spiritually healthier'.[88] It would provide a moral bonus to the population because it would satisfy the general inclination to solidarity and altruism.[89]

While solidarity as underlying the health service may be agreed on,[90] the values represented by the NHS are less clearly circumscribed, no doubt influenced by the changing policies of governments since the inception of the NHS.[91] Different themes have emerged over the years. Some of these themes have been described as values underpinning the NHS whereas others are rather policies or means for achieving these 'desirable ends'.[92] In contrast to policies, values, defined as aspirations or conceptions of the morally desirable,[93] tend to command universal support, are

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[85] Ministry of Health, *The National Health Service Bill* 1946 (Cmd 6761, 1946) paras 1-7.
[86] Social Insurance and Allied Services, *Beveridge Report* (Cmd 6404, 1942) and see also K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313, 325.
[87] J Harrington, 'Visions of Utopia: Markets, Medicine and the National Health Service' (2009) LS 376, 384 citing A Bevan, *In place of Fear* (Quartet Books, London 1990)106.
[88] ibid citing M Foot, *Aneurin Bevan – A Biography vol 1: 1897–1945* (MacGibbon & Kee 1962) 105.
[89] ibid.
[90] B Prainsack and A Buyx, *Solidarity – Reflections on an Emerging Concept in Bioethics* (Nuffield Council on Bioethics 2011) 29–30.
[91] R Klein, 'Values Talk in the (English) NHS' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 19.
[92] ibid 22.
[93] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research 1999).

essentially abstract and allow competing interpretations.[94] The principles on which the NHS was founded can be viewed in this light.[95] Seedhouse, for example, describes the beginnings of the NHS as 'political fudge' concealing a number of tensions. He argues that, despite the clash of political schools and professional interests at the creation of the NHS, the ambiguity of the conceptual foundations of the NHS may have enabled all stakeholders to feel some satisfaction at the time.[96] It is in the process of implementing these values where contentions occur, but their fuzziness also has advantages. As discussed later in this chapter, the haziness of the settlement values does not only allow a large degree of policy divergence but has also enabled policy-makers of different political persuasions to use them to explain and justify their policies.[97]

What, then, are the founding values of the NHS? The essence of the values of the Health Service was outlined by Bevan at the introduction of the National Health Service Bill in the House of Commons as 'to divorce the ability to get the best health advice and treatment from the ability to pay and to provide the people of Great Britain, no matter where they may be, with the same level of service'.[98] The leaflet, *The New National Health Service*, distributed to every household, confirmed Bevan's vision:

> It [the Health Service] will provide you with all medical, dental, and nursing care. Everyone – rich or poor, man, woman or child – can use it or any part

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[94] R Klein, 'Values Talk in the (English) NHS' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 22–23.
[95] ibid.
[96] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 12–13.
[97] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research 1999) 7–15; R Klein, 'Values Talk in the (English) NHS' in S L Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 22–23.
[98] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 19; see also Ministry of Health, *A National Health Service* (Cmd 6502, 1944) and Ministry of Health, *The National Health Service Bill* 1946 (Cmd 6761, 1946).

> of it. There are no charges except for a few special items … But it is not a charity. You are all paying for it, mainly as taxpayers.[99]

Although the objectives of the NHS have been further pronounced on by Royal Commissions[100] and expanded by later government documents[101] and the NHS Constitution,[102] it is possible to condense the early documents to four settlement values; comprehensiveness, universality, equity of access, and free at the point of delivery. The opacity and ambiguity of these concepts were apparent from the outset.[103] They need to be analysed in turn in order to understand how they have come to be connected with the new policies of 'efficiency' and 'freedom of (treatment) choice' in more recent times.

1.2.1 The value of comprehensiveness

Although the goal of the comprehensiveness of the service was accepted by the various stakeholders,[104] comprehensiveness could not be guaranteed, even from the inception of the NHS.[105] However, more importantly, without a definition of health how could the NHS ever be described as a comprehensive service? The opportunity to define health had been missed.[106] Although the Beveridge Report[107] and parts of the 1944 White Paper suggest the adoption of a broad definition of health, the lack

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[99] C Webster, *The National Health Service: A Political History* (2nd edn, OUP 2002) 24.
[100] See eg Royal Commission on the National Health Service (Cmnd 7615, 1979).
[101] See eg Secretaries of State for Health, Wales, Northern Ireland and Scotland, *Working for Patients* (Cm 555, 1989); Department of Health, *The NHS Improvement Plan: Putting People at the Heart of Public Services* (HMSO 2004); Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008); Department of Health *Personal Health Budgets: First Steps* (HMSO 2009); Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010).
[102] Department of Health, *NHS Constitution for England* (HMSO 2012) 1 which provides that the NHS is to remain a comprehensive service available to all, with access to the service being based on clinical need rather than the ability to pay but it is also to take account of existing health inequities in its promotion of equality.
[103] C Webster, *The National Health Service: A Political History* (2nd edn, OUP 2002) 22.
[104] ibid.
[105] ibid 23 stating that occupational health and school services were excluded.
[106] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 12.
[107] Social Insurance and Allied Services, *Beveridge Report* (Cmd 6404, 1942) which refers to the slaying of the five giants; want, ignorance, disease, squalor and idleness.

of clarity of the term makes the 'comprehensiveness' of a *health* service a rather suspect value.

Most theories of health claim that health is more than 'absence of disease or disability'.[108] As such, a health service would transcend clinical activity and consider people in their environmental context, or focus on wellness and empowerment rather than on morbidity and mortality. The lack of a definition of health played into the hands of the medical profession, leading to the conclusion that the NHS ended up 'little more than a medical service dressed up in fine language'.[109] As Klein comments, the NHS was 'designed to accommodate certain specific interests within the medical profession … [who] … obtained a monopoly of legitimacy among the health service providers: a unique position, reflected in the running of the NHS'.[110] Health service providers who were not medically qualified were largely excluded from public provision of healthcare.

Orthodox medical practitioners had, however, not always been a privileged group. In eighteenth-century Britain it may not have been easy to distinguish between the 'quacks' or unorthodox healers and the 'regulars'. Regular medicine did not enjoy the therapeutic success that would make it the automatic choice of patients.[111] It is only from the mid nineteenth century that medical doctors achieved the dominant position in healthcare provision to the detriment of other healthcare practitioners.[112] They were successful in their professionalisation, removing the fragmentary nature of the medical profession by engaging in self-regulation, controlling the education of

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[108] The Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19–22 June 1946, provides the definition of health as 'a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity'.

[109] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 12.

[110] ibid citing R Klein, *The Politics of the NHS* (2nd edn, Longman 1989) 28; S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 137–38.

[111] S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 87.

[112] British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 40.

medical students and requiring registration on a single national register.[113] This was achieved with the introduction of the Medical Act 1858 which set up the General Medical Council as the controlling body of all qualified medical doctors, [114] uniting them against unqualified rivals such as bonesetters, herbalists and itinerants.[115] The medical profession had 'a secure foothold in the bureaucratic apparatus of the state'.[116] It is therefore not surprising that the view of health that became dominant within the NHS was the medical concept of health, a concept where doctors and hospitals play the central role.[117] Although this meaning of health is disputed, it has exercised influence on the definition of the values of the NHS, the allocation of resources,[118] and on the position of CAM in the Health Service.

Definitions of health: Biomedicine versus complementary alternative medicine

Of the many different concepts of health, the medical model is probably the most restrictive, focusing on disease and disability, their causes and cure. It attempts to trace the pathways of disease, uncovering the pathological processes of disease and its effects and to understand the mechanisms of remedy.[119] 'It sees the body as a machine to be repaired by technical means', with illness resulting from pathological processes in the biochemical functions of the body.[120] The medical model attempts 'to uncover the underlying pathological processes and their effects', but the aetiology of many diseases is unknown so treatment is often reduced to an attempt to

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[113] M Saks, 'Political and Historical Perspectives' in T Heller and others (eds), *Perspectives on Complementary and Alternative Medicine* (Routledge Cavendish 2005) 68; J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 49.

[114] The Medical Act 1858, s 3 (repealed – now Medical Act 1983, s 1) created the General Medical Council which is responsible for the education and registration of medical practitioners; see Medical Act 1858, ss 15 and 17.

[115] B Turner, 'The End(s) of Scientific Medicine?' in P Tovey and others (eds), *The Mainstreaming of Complementary and Alternative Medicine* (Routledge 2004) xiii.

[116] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 85.

[117] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 270.

[118] ibid 272.

[119] M Bury, *Health and Illness* (Polity Press 2005) 2–3.

[120] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 272 citing R Illsey, 'Everybody's Business? Concepts of Health and Illness' in Social Science Research Council, *Health and Health Policy Priorities for Research* (SSRC 1977).

lessen the impact of symptoms and contain the illness rather than to cure.[121] From this it becomes clear that the medical model tends to excel at treating infectious diseases and acute or traumatic injuries; it excels at emergency care,[122] and is built around the treatment of acute or episodic health problems.[123]

The medical model is, however, less successful with the diagnosis and treatment of chronic, multifaceted and terminal illnesses which are rarely cured by biomedicine, exhaust current scientific knowledge and often require treatment accompanied by considerable side-effects.[124] It fails to recognise the limits of technologically oriented healing, creates feelings of dependence and leaves patients feeling alienated.[125] With advances in healthcare keeping people alive and controlling but not curing their chronic illnesses, and an increasing number of older people in the population with chronic health problems due to their exposure to risk factors over their lifetime,[126] a medical model of health may require rethinking.

A holistic healing paradigm, in contrast, views 'diseases as having multiple causes amenable to multiple therapeutic interventions through a variety of systems of care'.[127] In holism the goal is 'balance rather than simply a control of symptoms; subjective relief and not merely a favourable and scientifically measurable clinical

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[121] M Bury, *Health and Illness* (Polity Press 2005) 3–5.
[122] MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 2.
[123] The medical model leaves out of account emotional, social, economic and cultural components in its definition of health.
[124] MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 2–3.
[125] ibid 3.
[126] E Nolte and M McKee, 'Caring for People with Chronic Conditions: an Introduction' in E Nolte and M McKee in *Caring for People with Chronic Conditions* (OUP 2008) 2–3.
[127] MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 2–4 where the author contrasts CAM as adopting a wholeness or social paradigm of healthcare aiming at a non-mechanistic and non-reductionistic approach to the disease process with the reductionism (the reduction of illness to a set of physical symptoms) of biomedicine cf S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 8 stating that the term holism is subject to confusion as there is a version of biomedicine which also claims to be holistic.

outcome'.[128] The commonly understood meaning of holistic medicine is the notion that problems of ill-health involve the mind, body, and spirit of an individual, and holistic medicine is therefore an approach treating the whole person.[129]

CAM, which comprises a multitude of treatment modalities, takes a generally more holistic approach to health than the biomedical model. CAM therapies range from complete systems of healing such as acupuncture, traditional Chinese medicine and herbal medicine, to therapeutic modalities such as aromatherapy and spiritual healing, to diagnostic methods such as iridology and kinesiology and to self-help measures such as yoga and biofeedback.[130] According to Stone and Matthews, while this may mean that a CAM practitioner seeks to treat all levels of a patient's problem, the more common understanding is that a therapeutic intervention at one level will have a positive effect at other levels.[131] Coupled with the emphasis on the whole person, complementary alternative therapies importantly tend to place greater emphasis on active patient participation in a less disempowering therapeutic relationship between patient and practitioner, on self-responsibility and on individualised, patient-centred healthcare than the medical model.[132] Because of its

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[128] MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 2.

[129] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 10; S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 8.

[130] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 87–88; cf House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000) chapter 2 where the distinction is made between professionally organised alternative therapies, ie acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy, and complementary therapies such as aromatherapy, reflexology, hypnotherapy etc., and other therapies such as Ayurvedic Medicine, Traditional Chinese Medicine and various others including kinesiology and iridology favouring a philosophical approach and are indifferent to the scientific principles of conventional medicine.

[131] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 10 cf House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000) 2.12–2.15 which states that 'holistic medicine' is no more than good medical practice, that CAM is defined by its position outside conventional medicine rather than by any common philosophy and that a spectrum exists between reductionism and holism with conventional medicine and CAM spanning the whole spectrum.

[132] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 6 and 294–96; cf the theme of personalised healthcare of policy makers in recent years stressing responsibilisation of the patient with increasing emphasis on self-care and self-management, see 38–42.

emphasis on lifestyle, nutrition, self-care and emotional well-being, CAM has a preventive outlook, and with its emphasis on self-responsibility it is particularly suitable in chronic illness rather than in emergency care.[133]

'Comprehensiveness' within a medical paradigm

Although the medical model of health may have prevailed because of the missed opportunity of defining health, the National Health Service Act 1946 did not prohibit the provision of CAM under the NHS. Some groups of CAM practitioners had argued for inclusion in the National Health Service,[134] but entry was made subject to the reorganisation of CAM practitioners with recognised training schemes and also to them working as medical auxiliaries under the direction of the medical profession, a proposal which was rejected.[135] CAM could, however, still be provided by qualified medical practitioners as part of the NHS. Although the Medical Registration Bill 1858 had been intended to prevent the practice of non-orthodox medicine by medical practitioners, an amendment to the Bill instigated by Dr Quin, an influential doctor and homeopath, enabled the Privy Council to withdraw the right to award degrees from any university trying to dictate the type of medicine practised by its medical graduates.[136] Thus, under the Medical Act 1858, conventionally trained doctors can legally practise other types of medicine.[137] Conventionally trained medical practitioners, for example, provided complementary therapies in homeopathic hospitals, even prior to the beginning of the NHS.[138] However, with the exception of homeopathy provided by medical practitioners,[139]

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[133] MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 14.
[134] B Inglis, *Natural Medicine* (Collins, London 1979) 96–97 referring to herbalists who realised that the economic advantage of their cheaper remedies would disappear with the NHS dispensing medicines for free and thus argued for inclusion into the NHS.
[135] ibid.
[136] B Inglis, *Fringe Medicine* (Faber and Faber 1965) 80.
[137] C Zollman and A Vickers, 'ABC of Complementary Medicine' (1999) 319 BMJ 901, 903 argue that today such practice would have to be read subject to the standard of care in accordance with the *Bolam* standard.
[138] ibid 901.
[139] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 70–71 suggesting that public funding of homeopathy can be explained due to its link with influential clientele including the royal family.

NHS cover of CAM treatment was rare[140] because the medical establishment, through its trade union body the British Medical Association (BMA), and its medical licensing body the General Medical Council (GMC), kept control over any deviation from the biomedical model by orthodox practitioners, thus restricting the adoption of CAM treatments.[141]

1.2.2 The value of universality

Access to the National Health Service under the NHS Bill was to be available to *everyone* in England and Wales with no limitations according to financial means, sex, employment, vocation, area of residence, or insurance qualification.[142] Universality, originally opposed by the BMA as undermining opportunities for private practice, had been accepted as one of the values underlying the NHS. Bevan had referred to it as one of the purposes of the NHS: 'to provide the people of Great Britain, no matter where they may be, with the same level of service'.[143]

Universality appears a relatively unambiguous term. It is, however, linked with equity of access and may be confused with it as, without the availability of facilities and medical practitioners in all geographical areas, not *all* patients may be able to utilise the service.[144] Universalism has been interpreted as the value coming closest to the understanding of solidarity. It provides people with tranquillity and reassurance if they, in Bevan's words, 'have at the back of their consciousness the knowledge that not only themselves, but all their fellows have access when ill to best

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[140] British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 41 refers to qualified doctors practising osteopathy and members of the British Osteopathic Association; B Inglis, *Fringe Medicine* (Faber and Faber 1965) 110–11 referring to few qualified doctors practising osteopathy; the web site of the London College of Osteopathic Medicine <www.lcom.org.uk> accessed 25 October 2011 states that medical practitioners trained in osteopathy could become members of the original British Osteopathic Association since 1946.
[141] M Saks, 'Political and Historical Perspectives' in T Heller and others (eds), *Perspectives on Complementary and Alternative Medicine* (Routledge Cavendish 2005) 72; B Inglis, *Natural Medicine* (Collins 1979) 106; S Cant and U Sharma, *A New Medical Pluralism* (UCL Press 1999) 92.
[142] Ministry of Health, *The National Health Service Bill* 1946 (Cmd 6761, 1946) 3; R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 256.
[143] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 19.
[144] J Ovretveit, 'Values in European Health Care Markets' (1994) 4 European Journal of Public Health 294, 297.

that medical skill can provide'.[145] Universality therefore implies that people not receiving medical care now, but who may require such care in the future, still derive a benefit from the NHS.[146] According to New, the concept combines two subsidiary values within it, namely that of cohesion and togetherness, and of security and reassurance, which is achieved by ensuring that everyone is covered by the healthcare system.[147] Opting out, in the sense that tax can be withheld or reclaimed, is not possible. Universality is not affected by the paucity of provision of CAM within the NHS, whereas the paucity of provision has an adverse effect on equity of access.

1.2.3 The value of equity

The belief that equity underlies the National Health Service, that 'the health service should be for all the British people equally' has been a deeply cherished NHS principle.[148] As Dixon and others pointed out, it would be difficult to find any academic study regarding the principles underlying the NHS which would not include a reference to the importance of equity or fairness and social justice.[149] However, it is not often clear what equality or equal access to healthcare implies. While closely related to universality, which provides assurance of the availability of healthcare in times of need, equity, unlike universality, is concerned with the distribution of benefits in society and deals with the fairness of distribution.[150] Universality, therefore, will allow people to avail themselves of the health service

[145] J Harrington, 'Visions of Utopia: Markets, Medicine and the National Health Service' (2009) Legal Studies 376, 384 citing M Foot, *Aneurin Bevan – A Biography vol 1: 1897–1945* (MacGibbon & Kee 1962) 105.
[146] B New, *A Good Enough Service – Values, Trade-offs and the NHS* (Institute for Public Policy Research 1999) 49.
[147] ibid 27.
[148] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 61 citing C Ham, *Health Policy in Britain* (Macmillan 1982).
[149] A Dixon and others, 'Is the NHS Equitable? A Review of the Evidence' (2003) LSE Health and Social Care Discussion Paper Number 11, 5.
[150] B New, *A Good Enough Service – Values, Trade-offs and the NHS* (Institute for Public Policy Research, London 1999) 28.

whether or not they are able to pay for it, whereas equity of access is concerned with the fairness of distribution.[151]

There are a variety of ways in which equity can be interpreted. Only two of these will be discussed; geographical equity of access and equity of access according to needs.

Geographical equity of access

Geographical equity of access involves ensuring that there are facilities available in all areas, that medical practitioners are accessible in all areas and that there are no barriers preventing patients from accessing the facilities or practitioners.[152] It could be taken to include equity of resource distribution as well as equity of service distribution 'to ensure that people in all areas have the same opportunity of access to the same range of services' in order to reduce geographical inequalities of health.[153] There is, therefore, a contradiction when Webster can state that the NHS perpetuated the inequalities in healthcare provision it had inherited, mirroring the patterns in the distribution of wealth in the country. Thus the areas with the greatest problems of ill-health also received the worst health services: the better hospitals and greater concentration of General Practitioners were concentrated in areas around London whereas the least well provided areas were mainly the areas where heavy industry was located.[154]

While the geographical distribution of resources reflecting the relative health status of areas has now largely been achieved with the use of resource allocation

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[151] ibid.

[152] J Ovretveit, 'Values in European Health Care Markets' (1994) 4 European Journal of Public Health 294, 297; see also A Dixon and others, 'Is the NHS Equitable? A Review of the Evidence' (2003) LSE Health and Social Care Discussion Paper Number 11, 6 distinguishing equality of access where individuals have the same opportunity to use the health service from equality of utilisation which requires that they actually use the service and may be dependent on cultural or other factors.

[153] J Ovretveit, 'Values in European Health Care Markets' (1994) 4 European Journal of Public Health 294, 297.

[154] C Webster, *The National Health Service: A Political History* (2nd edn, OUP 2002) 57–58; see also S Cant and U Sharma, *A New Medical Pluralism* (UCL Press 1999) 30 where the authors refer to similar geographical differences in the provision of private CAM.

formulae,[155] equity in terms of access to the same package of healthcare has not been achieved.[156] Postcode rationing and local deviations from norms of provision are still common. Regarding the provision of CAM within the NHS a similar pattern is noticeable; equity of geographical access was contradicted by provision concentrated around the locations of the original homeopathic hospitals (London, Tunbridge Wells[157], Bristol and Liverpool) and greater provision in the affluent south of England[158] with postcode rationing making for local variation.

Equity of access according to need

Equity of access to healthcare linked with the notion of need also gives rise to ambiguity. Equity of access according to need implies distributive justice, that if people are not equal they shall not have equal shares of healthcare.[159] However, the ambiguity of this value stems from the definition of need. The lack of consensus regarding the interpretation of need makes it difficult to realise a fair healthcare system. Thus an equitable provision of healthcare can be made dependent on factors or proxies for need, such as the severity of ill-health, the capacity to benefit, social factors, age or time waiting for treatment.[160]

When interpreted in terms of the severity of ill-health, the worse a person's health status, the greater her need for treatment. That a person who is in greater need receives faster or more intensive treatment is recognised, for example, with the use

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[155] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 289 citing G Bevan, 'The Search for a Proportionate Care Law by Formula Funding in the English NHS' (2009) 25 Financial Accountability and Management 391.
[156] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 289.
[157] The Tunbridge hospital was closed by the West Kent PCT in 2009 and the Liverpool hospital finally closed in 2007.
[158] K Thomas and P Coleman, 'Use of Complementary or Alternative Medicine in a General Population in Great Britain. Results from the National Omnibus Survey' (2004) 26 Journal of Public Health 152, 153.
[159] B New, *A Good Enough Service – Values, Trade-offs and the NHS* (Institute for Public Policy Research 1999) 28.
[160] ibid 28.

of a 'triage' system in Accident and Emergency departments.[161] Need is therefore linked to the ill-health of a person.[162] A person who is not ill would not have any healthcare need, a view which defines the narrow medical model of health. This definition therefore limits the scope of the health services to medical treatments and excludes preventative[163] and also holistic care. A person's health status is, however, co-dependent on other factors[164] which ought to be taken into account when assessing need, in order to reduce inequities in health between different people. Differing needs due to underlying inequalities therefore demand unequal treatment.

Need may also be defined as the 'capacity to benefit'. Examples would be patients presenting at an earlier stage and thus with a greater chance of a better treatment outcome than patients presenting with more advanced disease. Thus, if need is defined in terms of a person's health status or degree of ill-health, then the later presenter has greater need, whereas if it is defined in terms of capacity to benefit, then the early presenter has the greater need.[165] Capacity to benefit, apart from taking into account the likely response of a patient to treatment, can also take into account other factors such as age or social factors. However, capacity to benefit from healthcare is also dependent on what health services are available to the patient. As Seedhouse argues, the existence or availability of a specific treatment in the NHS is a pre-requisite for a person's capacity to benefit.[166] Any potential alternatives to existing NHS treatment would therefore also have to be assessed in terms of a person's capacity to benefit.

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[161] J Ovretveit, 'Values in European Health Care Markets' (1994) 4 European Journal of Public Health 294, 298.
[162] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 30.
[163] ibid.
[164] Such factors could, for example, include emotional, social, economic and cultural factors, see eg C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 270–73; see eg Department of Health and Social Security, Black Report, *Inequalities in Health* (DHSS 1980); Department of Health, Acheson Report, *Independent Inquiry into Inequalities and Health* (HMSO 1998); Department of Health, *Tackling Health Inequalities: 2007 Status Report on the Programme for Action* (HMSO 2008).
[165] A Dixon and others, 'Is the NHS Equitable? A Review of the Evidence' (2003) LSE Health and Social Care Discussion Paper Number 11, 7.
[166] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 28.

The inconsistency of a generally accepted definition of need also renders equity open to different interpretations. Moreover, need defined in terms of ill-health or capacity to benefit protects the status quo, since meeting need is dependent on what is available to treat the sick. This definition of equity therefore excludes a wider definition of health and is restricted to the medical model.

1.2.4 The value of 'free' healthcare

Bevan intended the NHS to be a tax-financed service, free at the point of delivery,[167] recognised as an outstanding example of socialised medicine. He argued against charges since, if these were more than nominal, the less well-off would have to be exempted, thereby increasing administrative complexities.[168] However, the National Health Service Bill in 1946 already anticipated some user charges, such as for the renewal or repair of spectacles and dentures, for certain goods and articles (such as supplementary foods and blankets) provided in connection with maternity and child welfare, and for private rooms in hospitals.[169] However, charges have never contributed more than marginally to the income of the NHS, even after the advent of prescription charges.[170]

Although the Health Service Bill specifically mentioned the kinds of health services which were to be included, from hospital and specialist services to health centres and general practitioner services, supplementary services such as midwifery, maternity and child welfare and the provision of drugs and medicines,[171] it did not exclude CAM. The health service was to cover all 'necessary forms of healthcare',[172] but a clarification of what constitutes necessary healthcare was not provided.[173] Complementary alternative medicine may or may not be part of this necessary

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[167] C Webster, *The National Health Service: A Political History* (2nd edn, OUP 2002) 1 and 14.
[168] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 29.
[169] Ministry of Health, *The National Health Service Bill* 1946 (Cmd 6761, 1946) para 7.
[170] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 28.
[171] Ministry of Health, *The National Health Service Bill* 1946 (Cmd 6761, 1946) para 3.
[172] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 14 citing Ministry of Health, *A National Health Service* (Cmd 6502, 1944) paras 6–9.
[173] ibid 14.

healthcare[174] with the decision as to its availability not unrelated to this definitional haziness.

Patient choice played no role in the original NHS settlement. The role of patient choice is, however, understood as entwined with the market reforms of the NHS that commenced under the Thatcher government, to which the chapter now turns, which also had an impact on the publicly funded provision of CAM.

1.3. 'NHS plc': The new policies of the transformed NHS: efficiency and choice

Whilst rationing and priority-setting were not contemplated when the NHS was created, as it was expected that the demand for health services would gradually decrease once the unmet need had been satisfied, the opposite happened: the demand for medical services exceeded all expectations.[175] It was recognised early on that the NHS was not self-limiting in that its contribution to national health did not limit the demands upon it to a volume that could be fully met.[176] It is this demand for healthcare which led to the adoption of a new principle or policy goal, that of the cost containment of healthcare spending.[177] While values such as universality, equity and comprehensiveness of healthcare are values which tend to command universal support,[178] it is debatable whether cost containment can be described as such.[179] Cost

[174] KJ Thomas and others, 'Access to Complementary Medicine via General Practice' (2001) British Journal of General Practice 25, 28–29 stating that treatment provision of CAM within the GP practice in 1995 was privately and publicly funded.
[175] C Webster, *The National Health Service: A Political History* (2nd edn, OUP 2002) 29–30; D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 14; C Ham, *Health Policy in Britain* (6th edn Palgrave Macmillan 2009) 77.
[176] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 29 where the author refers to comments by the Guillebaud Committee set up in 1952 to inquire into the cost of the NHS.
[177] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 15.
[178] R Klein, 'Values Talk in the (English) NHS' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 22.
[179] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 15.

containment is a policy goal, a means to realising desirable ends.[180] In a national health service this goal can be achieved by different means such as not increasing funding to meet rising demand,[181] user charges,[182] reducing the quality of healthcare provided, reducing the varieties of healthcare included in the healthcare basket,[183] delaying elective healthcare services and, importantly, by means of improving efficiency.

In 1980, the Conservative Prime Minister, Margaret Thatcher, not content with patching the leaky roof of the old NHS – the 'NHS church' – began a radical reshaping of the NHS leading to the establishment of the internal market, the new business-like NHS – 'NHS plc'– in 1990.[184] Efficiency became the driving force in this new NHS. Despite the fierce campaign against the proposals launched by the doctors' trade union body, the BMA, the power of hospital consultants, seen as an obstacle to efficiency,[185] was reduced and replaced by managers with private-sector entrepreneurial experience, with the aim of making doctors more accountable for their performance.[186] New contracts for GPs were introduced. The long-standing close relationship between the medical profession, the BMA and the government had changed. As Klein points out: 'If the medical profession had shown itself strong in the distributional conflicts that followed the creation of the NHS in 1948, it had

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[180] R Klein, 'Values Talk in the (English) NHS' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 22.

[181] S Harrison and R McDonald, *The Politics of Healthcare in Britain* (Sage 2008) 15 stating that in the first forty years of the NHS little public policy debate existed about the need to manage the supply/demand relationship.

[182] eg prescription charges were first introduced in 1951, see R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 28.

[183] Complementary alternative therapy is considerably restricted in the NHS, see KJ Thomas and others, 'Access to Complementary Medicine via General Practice' (2001) British Journal of General Practice 25, 28–29 stating that treatment provision of CAM within GP practices in 1995 was privately and publicly funded; for restriction on the availability of dental services within the NHS, see C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 127.

[184] A Pollock, *NHS plc: The Privatisation of Our Healthcare* (Verso, London 2005) 41.

[185] ibid 36.

[186] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 38.

proved powerless to prevent the introduction of the new settlement … the medical profession lost its central place on the stage.'[187]

1.3.1 The policy goal of efficiency

The concept of efficiency contains a number of subsidiary elements[188] which lead to different interpretations. Efficiency matters since the size of the NHS budget is dependent on the state of the economy and the decisions on the priority of different spending programmes:[189] any increase in spending on health by the government means a reduction in expenditure on other areas such as education or defence.[190] The heading of efficiency has been related to its relevance in a competitive market, to ensure that providers operate at minimum costs[191] and also to the pursuit of cost-effectiveness.[192]

Efficiency and the healthcare market

The internal healthcare market was first proposed in 1989 in the White Paper *Working for Patients*[193] with providers competing for contracts with purchasers, a proposal which was subsequently translated into the NHS and Community Care Act 1990.[194] The reforms were designed to respond to the pressures on the service caused by rising demands and limited supply of resources.[195] The competitive nature of the market was intended to provide the incentive for providers to improve

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[187] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 161.
[188] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research 1999) 32–33 where the author also discusses the subsidiary element of macro-efficiency as a value relevant in the reduction of health inequalities not restricted to the treatment of ill-health.
[189] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 78.
[190] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 30; D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 81.
[191] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research, London 1999) 33.
[192] ibid 32.
[193] Department of Health, *Working for Patients* (HMSO 1989).
[194] National Health Service and Community Care Act 1990.
[195] J Dixon, 'Introduction: The Context' in J Le Grand and others (eds), *Learning from the NHS Internal Market, A Review of the Evidence* (King's Fund 1998) 1.

efficiency and become more responsive.[196] It was hoped that competition would lead to a reduction in costs and a lowering of public expenditure on the NHS. In order to stimulate competition, choice was given to the District Health Authorities (DHAs) and to the newly created GP fundholding practices[197] to purchase care from hospitals – the newly created NHS trusts – thus splitting the responsibility for purchasing and provision, both functions previously held in the hands of the DHAs.[198] Fundholding practices were given an incentive to be more efficient by being allowed to keep any savings from their budget to use for patient care.[199] The only choice patients were given was the choice of changing their GP.[200]

The problem at the core of the idea of the internal market in the NHS, where market decisions and impersonal market forces were to drive efficiency, was that it was not a market in the real sense but rather a quasi-market using market-like mechanisms.[201] The concept of the internal market turned into a managed market where policy-makers were 'active actors rather than passive spectators' of events.[202] In many areas in the country, competition between providers was non-existent.[203] If the logic of the market had been allowed to work then hospitals in areas of oversupply[204] or providing an unacceptable standard of care should have gone bankrupt, whereas instead policy-makers intervened to determine the future of health

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[196] A Oliver, 'The English National Health Service: 1979–2005' (2005) Health Economics 575, 577.
[197] With the budgets of GP fundholders being deducted from the budget allocation of the DHAs, see C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 41.
[198] ibid.
[199] J Dixon, 'Introduction: The Context' in J Le Grand and others (eds), *Learning from the NHS Internal Market, A Review of the Evidence* (King's Fund 1998) 6.
[200] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 152; cf C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 38 referring to the increased capitation payment which GPs received as designed to act as incentive to provide services demanded by patients.
[201] N Seddon, *Quite like Heaven? Options for the NHS in a Consumer Age* (Civitas 2007) 25.
[202] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 164.
[203] J Dixon, 'Introduction: The Context' in J Le Grand and others (eds), *Learning from the NHS Internal Market, A Review of the Evidence* (King's Fund 1998) 12.
[204] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 164 where the author cites the oversupply of London teaching hospitals as an example of where market principles were not allowed to work.

care, thus risking the weakening of the competition that was designed to drive down costs.[205]

A part of the market reforms to drive efficiency had been the introduction of fundholding GP practices.[206] Although fundholding may not have had a major economic impact on the local hospital trusts due to GPs' loyalty to them and the fact that the fundholders' budgets only represented a small proportion of the income of any trust, it enabled GPs to enlarge the scope of primary care.[207] Fundholders were able to use their resources to buy additional services for their patients, including CAM, which could be purchased from CAM practitioners working outside the practice.[208] They could refer their patients to osteopaths and chiropractors, as these practitioners had become state-regulated,[209] and could also employ CAM therapists in their practice using the resources of their funds for the employment of additional professional staff.[210] The logic of market competition therefore appears to have found more resonance in the purchasing of *additional* 'primary care' services by GP fundholders with no interference from the government.

No consensus has emerged on the impact of the internal market on the NHS regarding efficiency gains. Studies by economists, however, agree on the difficulty

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[205] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 43; N Seddon, *Quite like Heaven? Options for the NHS in a Consumer Age* (Civitas 2007) 26.

[206] Although entry into the GP fundholding scheme was discretionary rather than mandatory, by 1997 about 50% of GPs were members of fundholding practices, see R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn Radcliffe Publishing 2010) 174; see also J Dixon, 'Introduction: The Context' in J Le Grand and others (eds), *Learning from the NHS Internal Market, A Review of the Evidence* (King's Fund 1998) 11.

[207] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 165.

[208] C Zollman and A Vickers, 'ABC of Complementary Medicine: Complementary Medicine in Conventional Practice' (1999) 319 BMJ 901, 903; KJ Thomas and others, 'Developing Integrated CAM Services in Primary Care Organisations' (2003) 11 Complementary Therapies in Medicine 261, 261; see also the fitness to practise guidelines of the General Medical Council in 1995 in General Medical Council, *Good Medical Practice* 1995–1998, [28]–[29] which now permitted doctors to delegate medical care to non-registered health care staff as long as the doctor believed this to be in the best interest of the patient, and the delegating doctor remained accountable for her patient.

[209] Osteopaths Act 1993 and Chiropractors Act 1994.

[210] British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 44.

of demonstrating efficiency gains as a consequence of the internal market.[211] There are limitations in evaluating any measurable change in an entire healthcare system because of the confounding effects of other factors on the system such as the level of resources invested by the government at the time to smooth the implementation of the internal market.[212] Le Grand and others conclude in their analysis that overall very little changed with the introduction of the internal market although they found some minor improvements in efficiency.[213]

Efficiency as cost-effectiveness

Leaving aside macro-economic calculations of the efficiency of health interventions generally and concentrating specifically on medical (and also CAM) treatment, cost-effectiveness entails the importance of cost as well as the degree of effectiveness of specific treatments. Although the main objective of the NHS is to produce health,[214] another of its objectives should be to maximise the total quantity of health gain of the population.[215] As resources are limited it is necessary to use these resources in the most efficient manner to maximise health outcomes.[216]

The New Labour government developed its own policies for the reform of the NHS, distinct from the internal market of the previous government. The White Paper, *The New NHS*[217] included different mechanisms to increase efficiency.[218] In particular, the creation in 1999 of the National Institute for Clinical Excellence (NICE)[219] had

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[211] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 44.
[212] J Le Grand and others, 'The Reforms: Success or Failure or Neither?' in J Le Grand and others (eds), *Learning from the NHS Internal Market, A Review of the Evidence* (King's Fund 1998) 119.
[213] ibid 117–20; see also C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 45.
[214] Regarding the definition of health see 2.1.
[215] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research, London 1999) 32; AJ Culyer, 'Maximising the Health of the Whole Community: the Case For' (1997) BMJ 667, 667 cf J Harris, 'The Case Against: What the Principal Objective of the NHS Should Really Be' (1997) BMJ 667, 669 where the author argues that it is not the improved health outcome of the whole community that matters but what matters to the individual is her own improved health status.
[216] AJ Culyer, 'Maximising the Health of the Whole Community: the Case For' (1997) BMJ 667, 667.
[217] Department of Health, *The New NHS: Modern-Dependable* (HMSO 1997).
[218] C Ham, *Health Policy in Britain* (6th edn, Palgrave Macmillan 2009) 53.
[219] National Institute for Clinical Excellence (Establishment and Constitution) Order (SI 1999/220); NICE, *A Guide to Our Work* (NICE 1999), Introduction.

as one of its objectives the development of guidance based on clinically effective treatments and procedures which reach a threshold level of cost-effectiveness. Quality-Adjusted Life Years or QALYs are the method used by NICE in its cost-effectiveness assessments; they enable the quantification of the costs and health gains of the population which can be expected from different treatments.[220] Applying the QALY cost-effectiveness analysis to CAM is problematic for a variety of reasons, not least because of the prevalent medical healthcare model in the NHS and the assessment of effectiveness in accordance with this model.[221] It is also problematic because of the difficulty of the overall cost calculation of CAM, the importance of treatment outcomes rather than the healthcare process,[222] and the importance of increased life expectancy in the QALY calculation.[223]

Linked with the goal of efficiency the other major new policy goal emerging in the new NHS was patient choice. It is the development of the patient choice policies from 1989 onwards that will be discussed next.

1.3.2 The policy goal of patient choice

The Conservative government's White Paper *Working for Patients*,[224] which set in motion the market reforms in the NHS, linked these reforms with the objective of increasing choice for the patient, specifically 'greater choice of services

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[220] E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn, OUP 2009) 43 stating that QALYs not only measure the amount of extra life that a treatment generates but also its *quality.* A QALY is equivalent to one year of life in perfect health so that any treatment can be assessed on the basis of the number of extra QALYs it provides compared with another treatment and on the cost per QALY of these treatments. The lower the cost per QALY of a treatment compared to another, the better value for money the treatment is; see also J Harris, 'QALYfying the Value of Life' (1987) 13 J Med Ethics 117, 118; J Harris, 'The Case Against: What the Principal Objective of the NHS Should Really Be' (1997) BMJ 667, 669 suggesting that QALY calculations are concerned with the health gain of the community generally rather than with the benefit to the individual patient, making it more suitable for macro-level policies.

[221] NICE, *A Guide to Our Work* (NICE 1999), Introduction, which states that it was to encourage evidence-based practice that NICE was created by being specifically charged with the responsibility of providing authoritative, robust and reliable guidance on current best practice; see also discussion in Chapter 4.

[222] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 53–55 discussing the importance of the healthcare process.

[223] See Chapter 4.

[224] Secretaries of State for Health, Wales, Northern Ireland and Scotland, *Working for Patients* (Cm 555, 1989).

available'.[225] However, apart from having a 'real choice between GPs', the only option patients had was buying their healthcare outside the NHS, thus taking some of the pressure off the service.[226] Within the NHS the individual patient was not given additional power to make decisions;[227] rather it was a choice by the GP on behalf of the patient and was intended to facilitate competition amongst hospitals for non-urgent treatment.[228] General practice was to play an increasing role in assisting patient choice and directing resources to match patient needs throughout the NHS.[229] The patient had the choice of changing her GP if she did not approve of the use of resources on her behalf.[230]

The emphasis on choice as an instrumental aim by policy-makers to achieve the values of the NHS has been a legacy of the White Paper. This is despite the fact that when New Labour won the general election in 1997 initially there was no mention of choice at all.[231] New Labour's terminology rather than featuring the market, competition or choice[232] stressed the values of equity and also quality.[233] However, in 2000 with the introduction of the NHS Plan,[234] patient choice became an important theme. Patients' choices were to include the right to choose a GP based on information to be made available about GP practices,[235] patients were to have more options about accessing the NHS with a choice of emailing or phoning their GP

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[225] ibid.
[226] I Greener, 'Towards a History of Choice in UK Health Policy' (2009) 31 Sociology of Health and Illness 309, 315 citing Department of Health, *Working for Patients* (HMSO 1989) section 1.18.
[227] A Mold, 'Patient Groups and the Construction of the Patient-Consumer in Britain: A Historical Overview', (2010) 39 Journal of Social Policy 505, 514.
[228] R Robertson, 'Patient Choice', The King's Fund 2008, 2 <www.kingsfund.org.uk/document.rm%3Fid%3D7356> accessed 15 July 2011.
[229] I Greener, 'Towards a History of Choice in UK Health Policy' (2009) 31 Sociology of Health and Illness 309, 315 citing Department of Health, *Working for Patients* (HMSO 1989) section 7.1.
[230] R Klein, *The New Politics of the NHS* (4th edn, Pearson Education 2001) 162.
[231] I Greener, 'Towards a History of Choice in UK Health Policy' (2009) 31 Sociology of Health and Illness 309, 317.
[232] Secretary of State for Health, *The New NHS: Modern-Dependable* (CM 3807, 1999); R Klein, *The New Politics of the NHS* (4th edn, Pearson Education 2001) 195; DA Barr and others, 'The Claim for Patient Choice and Equity' (2008) 34 J Med Ethics 271, 271.
[233] Department of Health, *The New NHS: Modern-Dependable* (HMSO 1997).
[234] Department of Health, *NHS Plan: A Plan for Investment, A Plan for Reform* (HMSO 2000); I Greener, 'Towards a History of Choice in UK Health Policy' (2009) 31 Sociology of Health and Illness 309, 318.
[235] Department of Health, *NHS Plan: A Plan for Investment, A Plan for Reform* (HMSO 2000) 10(5).

practices for advice and booking appointments online[236] and a choice of hospital and date and time of hospital appointments.[237] Staff responsiveness in the NHS to individual patient needs[238] and patient choice became the new policies. Although rejecting the emphasis on competition within the internal market and abolishing GP fundholding, New Labour accepted some quasi-market principles by keeping the purchaser/provider split with the creation of Primary Care Trusts (PCTs) as main purchasers of healthcare services.[239] Rather than linking choice with market competition, New Labour claimed that patient choice enhanced equity and would lead to greater equality in the health service and a fairer distribution of access to health services.[240] Successive Department of Health Papers[241] confirm New Labour's vision of patient choice and equity with free choice of any hospital for treatment, including private hospitals,[242] and more choice of treatment options for patients with long-term conditions.[243] Patient choice was confirmed also in the NHS Constitution of 2009.[244] As Klein points out, the elements of the market were, however, also present in New Labour's policies not only with the choice for consumers but also money following the patient, competition between a plurality of diverse providers and practice-based commissioning.[245]

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[236] ibid 1.11.
[237] ibid 10.20.
[238] ibid 9.18.
[239] R Klein, *The New Politics of the NHS* (4th edn, Pearson Education 2001) 209.
[240] DA Barr and others, 'The Claim for Patient Choice and Equity' (2008) 34 J Med Ethics 271, 272 citing eg Department of Health, *Building on the Best: Choice, Responsiveness and Equity in the NHS* (HMSO 2003) while arguing that the claim of choice increasing equity ignores the causal explanation of healthcare inequity.
[241] Department of Health, *Choosing Health: Making Choices Easier* (HMSO 2004); Department of Health, *Choice Matters: Putting Patient in Control* (HMSO 2007); Department of Health, *NHS Choices: Delivering for the NHS* (HMSO 2008).
[242] Department of Health, *Choice Matters: Putting Patient in Control* (HMSO 2007) 6–8.
[243] Department of Health, *NHS Choices: Delivering for the NHS* (HMSO 2008) 14.
[244] Department of Health, *NHS Constitution for England* (HMSO 2009) 2a referring to the patient's right to choose his or her GP, his or her right to choose a hospital and his or her right to be informed and decide on treatment options and a right to treatments recommended by NICE.
[245] R Klein, *The New Politics of the NHS* (4th edn, Pearson Education 2001) 219.

Choice was again confirmed as a principle in *Equity and Excellence: Liberating the NHS*,[246] the White Paper published by the new coalition government in 2010, enabling choice 'through an information revolution'.[247] Specifically, patients were to have the choice of any qualified provider, choice of a consultant-led team, choice of GP practice, choice in care for long-term conditions and choice of treatment and, to make these choices about their care, patients are to have access to the information they want.[248] Patient choice is also enshrined in the new edition of the NHS Constitution for England[249] and the Health and Social Care Act 2012.[250] The language of the coalition government is more market-focused with an increasing role for private sector providers in community as well as hospital care,[251] shadowing the policies of the time when choice first reared its head: the emphasis is couched in terms of competition in the healthcare market.[252]

Patient treatment choice of CAM within the NHS

Interest in CAM experienced a considerable increase in the mid-1960s, possibly as part of an emerging medical counter-culture with a desire for alternative lifestyles associated with a rejection of scientific progress and professional experts within orthodox medicine.[253] Growing demand for CAM by patients may have also been linked to the desire to try out alternative therapies because of the perceived lack of efficacy and safety issues of orthodox treatments and to a challenge of professional experts.[254] However, provision of CAM within the NHS was largely restricted to the

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[246] Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010).
[247] ibid 4.
[248] ibid 2.20; see also Health and Social Care Act 2012.
[249] Department of Health, *NHS Constitution for England* (HMSO 2012).
[250] eg Health and Social Care Act 2012, s 20(1)(2)c and s 13I.
[251] BBC News, 'NHS competition extended to community care' at <www.bbc.co.uk/news/health-14205603> accessed 30 August 2012; see also Health Service Act 2012, s 75 referring to procurement, patient choice and competition.
[252] Department of Health, *Healthy Lives, Healthy People: Update and Way Forward* (HMSO 2011).
[253] S Fulder, *The Handbook of Alternative and Complementary Medicine* (OUP 1996) 16; M Saks, 'Political and Historical Perspectives' in T Heller and others (eds), *Perspectives on Complementary and Alternative Medicine* (Routledge Cavendish2005) 73.
[254] M Saks, 'Political and Historical Perspectives' in T Heller and others (eds), *Perspectives on Complementary and Alternative Medicine* (Routledge Cavendish 2005) 73; S Cant and U Sharma, *A*

homeopathic hospitals because of the general opposition of the medical profession and the BMA to alternative medicine.[255] The GMC was also opposed to the practice of unorthodox therapies[256] but relaxed its stance after 1983.[257]

With the introduction of the internal market in 1991 and the emphasis on choice, although it was more GP-led than patient-led choice, CAM started to become more widely available in the NHS.[258] Increasing consumer demand in the private sector had exerted an impact on orthodox medical practitioners, in particular GPs, with a greater number of GPs practising one or more alternative therapies themselves.[259] With the introduction of the new contracts, health authorities were able to reimburse

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New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State (UCL Press 1999) 25; J Le Fanu, *The Rise and Fall of Modern Medicine* (2nd edn, Abacus 2011) 424–25.

[255] British Medical Association, *Alternative Medicine: Report of the Board of Science and Education* (Chameleon Press 1986) 61–64 contrasting the scientific medical progress of orthodox medicine with primitive beliefs and outmoded practices or even cults of CAM; see generally M Saks, 'Political and Historical Perspectives' in T Heller and others (eds), *Perspectives on Complementary and Alternative Medicine* (Routledge Cavendish 2005) 75; cf J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 108 pointing out that the BMA's opinions on CAM are not necessarily representative of the medical profession as a whole.

[256] General Medical Council, *The Blue Book* (GMC 1963) 11; cf and see also B Inglis, *Natural Medicine* (Collins 1979) 106.

[257] General Medical Council, *The Blue Book* (GMC 1983) II, 10–11 stating that medical practitioners were not barred from practising other types of medicine as long as they had the appropriate knowledge or skill or the necessary experience in the particular 'branch of medicine' to avoid the risk of a finding of serious medical misconduct. The delegation of medical duties to non-registered healthcare personnel remained fraught with difficulty and continued to risk disciplinary proceedings so that overall most CAM continued to be provided privately by CAM practitioners; see generally J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 55; S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 92.

[258] British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 5–8 showing a more positive stance towards CAM and emphasising that under the Medical Act 1858 medical practitioners were permitted to practise whatever form of treatment, conventional or otherwise, they wished; British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 41 referring to the Faculty of Homeopathy, the British Osteopathy Association and the British Medical Acupuncture Society as examples of organisations for doctors practising and qualified in different non-conventional disciplines.

[259] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 69; M Saks, 'Political and Historical Perspectives' in T Heller and others (eds), *Perspectives on Complementary and Alternative Medicine* (Routledge Cavendish 2005) 75; see also S Fulder, *The Handbook of Alternative and Complementary Medicine* (OUP 1996) 47 referring to studies carried out between 1986 and 1988 which concluded that between 16% and 38% of GPs already practised some kind of complementary medicine.

GPs employing complementary therapists.[260] GP fundholding practices, on the other hand, could use their funds to purchase complementary therapies, for example from CAM practitioners working outside the practice.[261] GPs could also refer patients for CAM to osteopaths and chiropractors as these practitioners had become state-regulated.[262] Patient 'choice' was therefore at the discretion of the GP and publicly funded CAM could generally only be accessed via a GP.[263] Not surprisingly, the vast majority of CAM provision remained in the private sector.[264]

With New Labour the growth of CAM within the NHS was subjected to a more systematic and collective decision-making process.[265] The choice policy was now focusing on equity and reductions in health variation rather than the market with its competition. Although overall more CAM services were accessed through the NHS, these were paid for directly by the patients.[266] A survey carried out in 2001 established that now 50% of GP practices offered their patients some access to CAM treatments. However, the percentage of patients financially supporting these services, which they had accessed through the NHS, doubled.[267] NICE,[268] established by New Labour, promotes evidence-based medicine, and CAM therapies

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[260] British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 44 citing NHS (General Medical Services) Regulations (SI 1992/635) requiring GPs to take reasonable care to ascertain the appropriateness of delegation of patient care to a non-conventional therapist.

[261] C Zollman and A Vickers, 'ABC of Complementary Medicine: Complementary Medicine in Conventional Practice' (1999) 319 BMJ 901, 903; KJ Thomas and others, 'Developing Integrated CAM Services in Primary Care Organisations' (2003) 11 Complementary Therapies in Medicine 261, 261.

[262] Osteopaths Act 1993 and Chiropractors Act 1994.

[263] C Zollman and A Vickers, 'ABC of Complementary Medicine: Complementary Medicine in Conventional Practice' (1999) 319 BMJ 901, 901.

[264] KJ Thomas and others, 'Use and Expenditure on Complementary Medicine in England: a Population based Survey' (2001) 9 Complementary Therapies in Medicine 2, 6 estimating that in 1998 90% of CAM consultations were provided privately with the cost of NHS-funded CAM amounting to approximately £50–55 million.

[265] S Halpern, 'Points of Engagement: The Integration of Complementary and Alternative Medicine into NHS Primary Care' in M Pinder (ed), *The Foundation of Integrated Medicine* (Arch Press 2001) 6.

[266] ibid 17.

[267] KJ Thomas and others, 'Trends in Access to Complementary or Alternative Medicines via Primary Care in England: 1995–2001 Results from a Follow-up National Survey' (2003) 20 Family Practice 575, 575.

[268] National Institute for Clinical Excellence (Establishment and Constitution) Order (SI 1999/220).

which were to be available on the NHS had to be scientifically validated.[269] In its response to the Report by the House of Lords Science and Technology Committee on CAM,[270] the New Labour government at the time emphasised that it supported the evaluation of CAM therapies by NICE[271] but added that only once a therapy had gained a critical mass of evidence to support its efficacy should the NHS and the medical profession ensure that the public had access to it.[272]

Patient choice of CAM treatment is being supported by the coalition government, at the time of writing, as a policy goal rather than depending on principles of evidence-based medicine.[273] Funding decisions on CAM are to be left to local decision-makers, whether PCTs or Clinical Commissioning Groups (CCGs), and the role of NICE which had been created[274] to establish uniform standards of treatment across the NHS is to be reduced. It is therefore likely that, with the demand for CAM by patients at present not being satisfied by public funding, NHS expenditure on CAM will increase. Personal health budgets, which were introduced in November 2012, will provide patients affected by chronic conditions with greater choice of treatment,[275] and enable them to purchase health-related services either directly or through a third

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[269] Department of Health, *Government Response to the House of Lords Select Committee on Science and Technology's Report on Complementary Medicine* (HMSO 2001) [4]; see also House of Commons, *Report of the Science and Technology Committee, Evidence Check 2: Homeopathy* (HMSO 2010) [77] recommending that homeopathy, since it is non-efficacious, should be withdrawn from the NHS; see also L Rose and E Ernst, 'What Does the NHS Spend on Complementary Medicine?' [2010] 21 Prescriber 9, 9 stating that funding of the homeopathic hospitals, for example, declined sharply between 2005 and 2008 with several PCTs discontinuing funding of homeopathy altogether.

[270] House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000).

[271] Department of Health, *Government Response to the House of Lords Select Committee on Science and Technology's Report on Complementary Medicine* (HMSO 2001) [5].

[272] ibid cf A Dixon, *Regulating Complementary Medical Practitioners* (The King's Fund 2008) 56 <www.kingsfund.org.uk/publications/who_paper.html> accessed 4 November 2011 which reported that access to publicly funded CAM services remained variable and depended on local purchasing policies, with PCTs setting their own priorities for treatments available to patients in their locality; see also Chapter 4.

[273] Department of Health, *Government Response to the Science and Technology Committee Report*, *'Evidence Check 2: Homeopathy'* (HMSO 2010) [9] stating that efficacy cannot be the most important factor when selecting treatment; rather, the overriding reason for NHS provision of homeopathy was that homeopathy provided patient choice.

[274] National Institute for Clinical Excellence (Establishment and Constitution) Order (SI 1999/220); NICE, *A Guide to Our Work* (NICE 1999), Introduction.

[275] C White, 'Do Personal Health Budgets Lead To Better Care Choices?' (2011) BMJ 343.

party.[276] In pilots carried out, patient choices have included aromatherapy and other CAM treatments.[277]

Current political discourse therefore demonstrates enthusiasm for treatment choice in the NHS. At the same time patient choice has been attacked for what it represents. It is challenged because it is seen to be in conflict with the traditional values of the NHS as inducing inequality and because it is seen as a proxy for policies of marketisation and privatisation such as efficiency and competition.[278] Pollock, for example, claims that the new 'NHS plc' has abandoned the founding principles of the NHS of comprehensiveness, universality and equity.[279] According to Fotaki, it is the expansion of the market and the marketisation policies of choice, competition and efficiency which are perceived as having a detrimental effect on the traditional values of the NHS.[280] Yet, other writers argue that despite these new policies the English NHS is performing well when measured against its core values.

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[276] Department of Health (2012) *Personal Health Budgets* update, *Winter 2012* <https://www.wp.dh.gov.uk/publications/files/2013/01/PBUnewsletterDec2012.pdf> accessed 6 January 2013.

[277] C White, 'Do Personal Health Budgets Lead To Better Care Choices?' (2011) BMJ 343, 344.

[278] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

[279] A Pollock, *NHS plc: The Privatisation of Our Healthcare* (Verso 2005) 78–79 stating that long-term residential care and routine optical care are no longer provided, and only adults fortunate enough to live near a dentist willing to work at NHS rates are still able to receive NHS dentistry, affecting the claim to comprehensiveness. Universality is no longer a given, as the emphasis is increasingly on decentralisation and choice. Equity of access has disappeared through the abandonment of comprehensiveness with less well-off people having to pay the same as the affluent for long-term care, optical care and dentistry.

[280] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006); D Hunter, 'The Case against Choice and Competition' (2009) Health Economics, Policy and Law 489; DA Barr and others, 'The Claim for Patient Choice and Equity' (2008) 34 J Med Ethics 271; A Oliver and J Evans, 'The Paradox of Promoting Choice in a Collectivist System' (2005) J Med Ethics 187; A Pollock, *NHS plc: The Privatisation of Our Healthcare* (Verso 2005) 78–79.

The continuity between the old and the new NHS is preserved[281] as policy-makers of different political persuasion have endorsed the founding values of the NHS.[282]

These challenges to patient choice are examined, concentrating on choice in the primary care sector as being most relevant in the context of CAM. The following discussion explores the possibility of whether policy-makers, rather than using patient choice as a proxy for privatising or quasi-privatising the NHS, may be using it as a policy mechanism hiding other political goals and intentions while at the same time attempting to affirm the underlying values of the NHS.

1.4. Challenges to patient choice

Opponents of choice regard it as inextricably linked with market economies, where choice is a proxy for competition and efficiency, marketisation and ultimately privatisation. As Pollock claims: 'The NHS is being dismantled and privatised … The disaster that is unfolding is overwhelming in its complexity and magnitude … [The NHS] has been made into a laboratory for market-based policy prescriptions.'[283] It is, however, questionable to what extent a policy of patient choice in a publicly funded healthcare system should be viewed exclusively as a proxy for marketisation policies and whether it may not be a rhetorical device by policy-makers concealing different political intentions.[284]

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[281] R Klein, 'Values Talk in the (English) NHS' in SL Greer and D Rowland (eds), *Devolving Policy, Diverging Values: The Values of the United Kingdom's National Health Services* (Nuffield Trust 2007) 19; A Dixon and J Le Grand, 'Is Greater Patient Choice Consistent with Equity? The Case of the English NHS' (2006) J Health Serv Res Policy 162; J Le Grand, 'Choice and Competition in Publicly Funded Healthcare' [2009] Health Economics, Policy and Law 479.

[282] A Oliver, 'The English National Health Service: 1979–2005' [2005] Health Economics 575, 576 pointing out that even Thatcher at the height of her political power chose not to move away from the principles of the NHS; DA Barr and others, 'The Claim for Patient Choice and Equity' (2008) 34 J Med Ethics 271; see also Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008); Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010); Department of Health, *Liberating the NHS: greater choice and control, a consultation on proposals* (HMSO 2010).

[283] A Pollock, *NHS plc: The Privatisation of Our Healthcare* (Verso 2005) 77–78, 224.

[284] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

1.4.1 Choice as a proxy for marketisation policies

Concentrating on the primary care level where most CAM is delivered, for choice to be possible it is a prerequisite that there must be a reasonable number of primary care providers from which the patient can choose.[285] It is difficult to imagine meaningful choice unless there is competition amongst providers for patients.[286] The NHS healthcare market has of course never been a real but rather a quasi-market. In this quasi-market, regarding NHS primary care[287], the GP who provides the better service[288] and is more responsive to patient demand may attract more patients and will continue in business as long as the services provided are also efficient. Patients who are dissatisfied with the services of their GP have the opportunity to switch GP practices.[289] Thus, at least in theory, patient choice may lead to competition between providers which in turn may promote efficiency.[290]

Evidence, however, suggests that to provide choice there would need to be an increase in the number of primary care providers in the NHS.[291] Choice has so far been limited in many areas because of closed or 'open but closed' GP lists,[292] with practices refusing patients if there are no spaces for new patients or the patients are from outside their catchment area. The market argument that healthcare providers

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[285] D Hunter, 'The Case against Choice and Competition' [2009] Health Economics, Policy and Law 489, 490.
[286] J Le Grand, 'Choice and Competition in Publicly Funded Healthcare' [2009] Health Economics, Policy and Law 479, 482.
[287] Where also most of CAM would be located.
[288] For example by also providing CAM out of practice funds.
[289] J Le Grand, 'Choice and Competition in Publicly Funded Healthcare' [2009] Health Economics, Policy and Law 479, 482.
[290] ibid 483.
[291] To what extent the number of primary care providers will increase substantially due an increasing number of private providers under the Health and Social Care Act 2012, s 75 remains to be seen.
[292] A Coulter, 'Do Patients Want a Choice and Does It Work?' (2010) 341 BMJ 973, 974; see also generally Royal College of General Practitioners 'It's Your Practice, a Patient Guide to GP Services' (2011) <www.nhs.uk/choiceintheNHS/Yourchoices/GPchoice/Documents/rcgp_iyp_full_booklet_web_version.pdf> accessed 5 March 2012; see generally Department of Health, *Our Health, Our Care, Our Say: A New Direction for Community Services.* Cm 6737 (HMSO 2006) which proposed opening up GP practice lists and providing incentives for GPs to set up practices in areas that were under-supplied.

who offer a choice of treatment, including CAM, will attract more patients and prosper, has therefore been hardly relevant.[293]

Evidence also suggests that although choice of GP was a policy objective since the healthcare reforms in 1990,[294] it was rarely enacted by patients switching practices.[295] Patients prefer to be treated locally and, when choosing their GP, tend to choose the GP closest to their home rather than on the basis of other criteria.[296] In any case, in order to have a real choice on such other criteria, for example, whether a practice provides CAM services and whether these services are NHS funded, information is crucial. As long as this information is not freely available competition will be stifled. There will be increased cost to provide this information and to provide support to make the information accessible to patients.[297]

1.4.2 Choice as proxy for efficiency

Rather than just the opportunity to choose a GP there is considerably more evidence that patients wish to be involved in individual treatment decisions[298] and have

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[293] cf Department of Health, *Operational Guidance to the NHS: Extending Patient Choice of Provider* (2011) 4 <www.dh.gov.uk/publications> accessed 1 September 2012 referring to the policy of the current coalition government aimed at increasing the numbers of such providers by extending patient choice from April 2013 to 'any qualified provider' in the NHS that meets NHS requirements for service quality. Providers of musculo-skeletal services for back and neck pain are considered for potential inclusion. If these are not salaried NHS employees a cost reduction for the NHS is possible.

[294] Choice of GP had at least in theory been available since 1948, see I Greener, 'Towards a History of Choice in UK Health Policy' (2009) 31 Sociology of Health and Illness 309, 313; R Robertson, 'Patient Choice' (The King's Fund 2008) 1 <www.kingsfund.org.uk/document.rm%3Fid%3D7356> accessed 15 July 2011.

[295] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 67.

[296] A Coulter, 'Do Patients Want a Choice and Does It Work?' (2010) 341 BMJ 973, 974; I Greener, 'Are the Assumptions Underlying Patient Choice Realistic?: A Review of the Evidence' (2007) British Medical Bulletin 1, 5.

[297] J Le Grand, 'Choice and Competition in Publicly Funded Healthcare' [2009] Health Economics, Policy and Law 479, 486; see also Royal College of General Practitioners 'It's Your Practice, a Patient Guide to GP Services' (2011) <www.nhs.uk/choiceintheNHS/Yourchoices/GPchoice/Documents/rcgp_iyp_full_booklet_web_version.pdf> accessed 5 March 2012; NHS Choices, 'GP Choice' (2012) <www.nhs.uk/choiceintheNHS/Yourchoices/GPchoice/Pages/ChoosingaGP.aspx> accessed 5 March 2012.

[298] M Fotaki and others, 'What Benefits Will Choice Bring To Patients? Literature Review and Assessment of Implications' (2008) J Health Serv Res Policy 178, 181.

information about available treatment options.[299] Most patients place greater value on involvement in choosing their treatment or treatment package.[300] As will be shown below, a choice of treatment in the primary care sector may, however, not lead to a reduction in cost or greater efficiency.

To be able to make a treatment choice, patients require information about the variety of possible treatments and their different risks and outcomes. While choice of treatment is likely to be less important for patients in acute and life-threatening medical situations, where the patient is particularly vulnerable and dependent on the expertise of the physician,[301] much more of the time in general practice is spent on patients with chronic, not time-limited conditions,[302] where recovery is impossible or at least unlikely in the near future and requires ongoing management over a period of years.[303] In order to exercise treatment choice the information requirements of these patients, often affected by several co-existing chronic health problems, will be extensive. However, there is often insufficient evidence available about the competing advantages and drawbacks of treatments for multiple conditions.[304] Studies among patients in general practice have shown that patients are not

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[299] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 101.

[300] A Coulter, 'Do Patients Want a Choice and Does It Work?' (2010) 341 BMJ 973, 974; see also E Nolte and M McKee, 'Caring for People with Chronic Conditions: An Introduction' in E Nolte and M McKee (eds), *Caring for People with Chronic Conditions:* A *Health System Perspective* (Open University Press 2008) 3–4 stating that patients with chronic, long-term conditions are particularly likely to value treatment choice because of the lasting impact of the illness or illnesses on their physical, psychological and social functioning, requiring them to alter their behaviour and engage in activities promoting their physical and psychological well-being.

[301] S Watt, 'Clinical Decision-making in the Context of Chronic Illness' [2000] Health Expectations 6, 6.

[302] E Nolte and M McKee, 'Caring for People with Chronic Conditions: An Introduction' in E Nolte and M McKee (eds), *Caring for People with Chronic Conditions: A Health System Perspective* (Open University Press 2008) 3 where the authors refer to T Wilson and others, 'Rising to the Challenge: Will the NHS Support People with Long-Term Conditions?' (2005) 330 BMJ 657 stating that people with chronic illness account for 80% of general practice consultations in England.

[303] S Watt, 'Clinical Decision-making in the Context of Chronic Illness' [2000] Health Expectations 6, 9 suggesting that treatment expectations are usually remission or control of symptoms, a delay in the progression of the disease or a prevention of secondary complications and rarely curative so that patients will want to make trade-offs regarding the different adverse effects of different treatments and the impact on their life.

[304] ibid 10.

sufficiently informed to make choices,[305] and this is one of the most common causes of dissatisfaction of patients.[306]

While patients are likely to benefit from being given information enabling them to make choices, the provision of this information is likely to add considerable costs. Not only is it likely to necessitate extending the allocated consultation time in the GP practice, it may also require patient choice advisors [307] and decision aids to improve the patients' understanding of, and help them with, their treatment options.[308] It might require a complete re-designing of the consultation process, with patients having to be referred to patient choice advisors and GPs having to incur additional costs to employ more staff.[309] Providing information and support to patients to enable them to arrive at sensible choices about their healthcare is therefore likely to lead to a significant increase in resources rather than enabling cost containment.

Whether patient choice really leads to efficiency gains in the primary healthcare sector is therefore far from clear,[310] unless efficiency gains could possibly be

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[305] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 101; M Fotaki and others, 'What Benefits Will Choice Bring to Patients? Literature Review and Assessment of Implications' (2008) J Health Serv Res Policy 178, 181.

[306] A Coulter, 'Do Patients Want a Choice and Does It Work?' (2010) 341 BMJ 973, 974; see also J Ovretveit, 'Values in European Health Care Markets' (1994) 4 European Journal of Public Health 294, 298 suggesting that it may also be one of the reasons why patients turn to CAM, because they are dissatisfied with losing control over decisions about their care in the conventional health setting.

[307] I Greener, 'Are the Assumptions Underlying Patient Choice Realistic?: A Review of the Evidence' (2007) British Medical Bulletin 1, 6; J Le Grand, 'Choice and Competition in Publicly Funded Healthcare' [2009] Health Economics, Policy and Law 479, 484; M Fotaki and others, 'What Benefits Will Choice Bring to Patients? Literature Review and Assessment of Implications' (2008) J Health Serv Res Policy 178, 182.

[308] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 122.

[309] I Greener, 'Are the Assumptions Underlying Patient Choice Realistic?: A Review of the Evidence' (2007) British Medical Bulletin 1, 6.

[310] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 115 arguing that efficiency gains of new patient choice schemes are difficult to assess because they may be accompanied by increased NHS funding.

achieved by moving some of the costs of treatment to the patient[311] by, for example, enabling access to CAM services through the primary care sector on the understanding that the patient will have to bear the costs of these services.[312] The concern with patient choice as proxy for marketisation policies is of course the concern that market reform will lead to privatisation or quasi-privatisation[313] where efficiency will become the driving force, leading to conflict and tension with the traditional values of the NHS, particularly the value of equity.[314] However, policy-makers have tended to justify their policies as supportive of the original settlement.[315] In this light, the antagonism towards patient choice in the English NHS as leading to inequity and therefore undermining one of its core values also needs to be scrutinised.

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[311] ibid 117.

[312] Thus supporting patient choice of CAM could also be used as a covert strategy to curtail costs, although such a solution would favour the better-off. Given that the holistic healthcare model of CAM favours individual responsibility for health, such a strategy might well be compatible with the views of government health policy-makers, see HA Baer, 'Why Is the Australian Government Interested in Complementary Medicine? A Case Study of Economic Rationalism' (2007) 12 Complementary Health Practice Review 167, 168 arguing that the growing legitimation of CAM in Australia is a strategy to curtail costs and parallels the advent of a policy of economic rationalism.

[313] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

[314] Efficiency might conflict with equity, defined as equal geographical access, as it is likely to be more expensive to treat people living in remote rural areas and to enable them to have access to the same package of healthcare as city dwellers. Efficiency might also affect equity, defined as unequal shares of healthcare depending on need, because the very 'needy' such as the elderly or disabled are likely to use a much larger share of the overall health budget. If the most 'needy' are considered to be those who are most at risk of immediate death, an efficient use of resources might encourage letting the most seriously ill die in order to stop the drain on resources and improve the aggregate health of the less ill; see J Harris, 'The Case Against: What the Principal Objective of the NHS Should Really Be' (1997) BMJ 667, 669-672 and M Fotaki, 'Patient Choice and Equity in the British National Health Service: Towards Developing an Alternative Framework' (2010) 32 Sociology of Health and Illness 898, 901; cf B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research 1999) 16 arguing that equal access to healthcare, both in terms of geographical equality of access to the same package of healthcare and also according to the various understandings of need, can only be achieved in a utopian world of unlimited resources; see also generally B Rumbold and others, *Rationing Health Care* (Nuffield Trust 2012) <www.nuffieldtrust.org.uk/publications/rationing-health-care> accessed 20 October 2012.

[315] A Oliver, 'The English National Health Service: 1979–2005' (2005) Health Economics 575, 576 suggesting that this may well be because of the value placed by the public on the principles underlying the NHS.

1.4.3 Choice and inequity

The apparent tension between choice and equity mirrors the conflict between individualist and the collectivist values underlying the NHS. Patient choice or individualist demand is challenged as being in tension with healthcare, which aims to be egalitarian.[316] Choice is attacked as the emphasis ought to be on the fair treatment of every patient given the available resources. Only if NHS resources were unlimited could every patient's preferences be satisfied.[317] In a healthcare system with limited resources the range of options available will have to be curtailed in order to achieve equality of provision of the core services.[318] Because of the inherent ambiguities in the definition of equity, however, patient choice is able to co-exist with equity. The haziness of the settlement value helps policy-makers to explain and justify their choice agenda. Geographical equity of access, equity of access according to need and equity in terms of patients' unequal capabilities and health literacy serve as examples.

As has been argued, geographical equity of access in terms of the distribution of resources reflecting health status has largely been achieved equalising the capacity of PCTs to meet local needs.[319] Defined in terms of equity of access to the same packages of healthcare, local variations in healthcare packages exist and patients are able to access specific treatments in one area but not in another.[320] These geographical inequalities in access to choice only became apparent following the

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[316] B New, *A Good Enough Service – Values Trade-offs and the NHS* (Institute for Public Policy Research 1999) 44.
[317] A Oliver and J Evans, 'The Paradox of Promoting Choice in a Collectivist System' (2005) J Med Ethics 187, 187.
[318] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 16–17; M Fotaki, 'Patient Choice and Equity in the British National Health Service: Towards Developing an Alternative Framework' (2010) 32 Sociology of Health and Illness 898, 901; A Oliver and J Evans, 'The Paradox of Promoting Choice in a Collectivist System' (2005) J Med Ethics 187, 187.
[319] R Klein, *The New Politics of the NHS: From Creation to Reinvention* (6th edn, Radcliffe Publishing 2010) 289.
[320] ibid.

introduction of patient choice policies.[321] Freedom of choice for patients advocated by policy-makers at the macro-level contradicts the 'postcode rationing' of specific healthcare services at the meso-level.[322] However, much depends on how geographical equity is defined.

A still greater tension appears to exist between equity of access according to need and choice. Whether need is defined in terms of a person's negative health status or in terms of a person's capacity to benefit, providing choice may impact on the overall availability of services in a healthcare system with limited resources. Greater choice in a resource-constrained system will therefore be at the expense of some users judged less needy, whether they are considered to be less in need of acute assistance or less likely to benefit from treatment. However, any lack of consensus regarding the interpretation of need unwittingly assists the proponents of choice. Needs-assessment is controversial:[323] a definition of need may not be a purely medical assessment but may include social and moral judgments.[324] An assessment of capacity to benefit, for example, may lead to the exclusion of older or poorer patients and those with a variety of health problems but a definition of need is also dependent on what the healthcare professional or organisation believes ought to be provided.[325]

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[321] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 89.

[322] PCTs set their own priorities for treatments which are available to patients in their locality, with CAM often being classified as low-priority treatment and only funded on an exceptional case basis, see chapter 4.

[323] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 31.

[324] J Ovretveit, 'Values in European Health Care Markets' (1994) 4 European Journal of Public Health 294, 298.

[325] D Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (John Wiley & Sons 1995) 27–31.

Choice and lack of 'voice'

Inequitable access to NHS healthcare may also refer to patients having unequal capabilities and differential knowledge with which to make choices.[326] Differences in health literacy and health-seeking behaviour between different socio-economic groups have been adduced as explanation.[327] Patients in higher socio-economic groups have also been shown to be more able to absorb and act upon information, which is often presented in an unfamiliar language by healthcare professionals. They have greater self-confidence in the consultation room and are in possession of more information about their health and their entitlements, and where and when to access services.[328] In Hirschman's terminology, these patients are able to use their 'voice' to demand their choice of service but may also use the threat of 'exit' from the NHS.[329] This apparent inequity can be countered by extending patient choice to the less well-off, as everyone would then have the option of 'voice' and 'exit' which would reduce the inequities that exist in the NHS.[330] Giving patients of lower socio-

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[326] A Dixon and J Le Grand, 'Is Greater Patient Choice Consistent with Equity? The Case of the English NHS' [2006] J Health Serv Res Policy 162, 163.

[327] A Dixon and others, 'Is the NHS Equitable? A Review of the Evidence' (2003) LSE Health and Social Care Discussion Paper Number 11, 27 where the authors, cite as an example a lack of awareness of family history of heart disease in lower socio-economic groups; M Fotaki, 'Patient Choice and Equity in the British National Health Service: Towards Developing an Alternative Framework' (2010) 32 Sociology of Health and Illness 898, 902.

[328] A Dixon and J Le Grand, 'Is Greater Patient Choice Consistent with Equity? The Case of the English NHS' (2006) J Health Serv Res Policy 162, 163; see also A Dixon and others, 'Is the NHS Equitable? A Review of the Evidence' (2003) LSE Health and Social Care Discussion Paper Number 11, 25 arguing that these patients get more out of the health service because they know how to work the system, because they are more likely to have family or friends who work in the health services; see also KJ Hunt and others, 'Complementary and Alternative Medicine Use in England: Results from a National Survey' (2010) Int J Clin Pract 1496, 1496–1502 suggesting that better-off patients can gain access to private healthcare and with CAM being mostly only available privately, the majority of CAM users tend to be patients in higher socio-economic groups.

[329] A Dixon and others, 'Is the NHS Equitable? A Review of the Evidence' (2003) LSE Health and Social Care Discussion Paper Number 11 citing A Hirschman, *Exit, Voice and Loyalty* (Harvard University Press 1970).

[330] DA Barr and others, 'The Claim for Patient Choice and Equity' (2008) 34 J Med Ethics 271, 272 citing eg Department of Health, *Building on the Best: Choice, Responsiveness and Equity in the NHS* (HMSO 2003); M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 117; M Fotaki, 'Patient Choice and Equity in the British National Health Service: Towards Developing an Alternative Framework' (2010) 32 Sociology of Health and Illness 898.

economic groups a 'voice' will involve providing them with information about choices and helping them to communicate with healthcare professionals who are able to elicit and understand their concerns.[331] At the same time the original NHS settlement value is being defended.[332]

The need by policy-makers to rely on the ambiguities and tensions of the traditional values of the NHS to justify their policies is no doubt due to the importance placed by the public on the principles underlying the NHS, so that any explicit movement away from them could cause significant political damage.[333] More recently the political discourse has turned from patient choice to the specific patient treatment choice policies of personalised healthcare and personal health budgets with their greater openness to CAM. It is suggested that these policies have equally been defended by policy-makers of different political parties as adhering to the founding principles of the NHS.

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[331] M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO, 2006) 122.

[332] New Labour used the argument of patient choice in defence of equity, see M Fotaki, 'Patient Choice and Equity in the British National Health Service: Towards Developing an Alternative Framework' (2010) 32 Sociology of Health and Illness 898, 901; see also M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 122. However, to give patients of lower socio-economic groups voice and choice will require considerable support to avoid them being disadvantaged, and allocating professional special support for patients to aid in decision-making has considerable cost implications and requires additional resources; see I Greener, 'Are the Assumptions Underlying Patient Choice Realistic?: A Review of the Evidence' (2007) British Medical Bulletin 1, 6–7; M Fotaki and others, 'What Benefits Will Choice Bring to Patients? Literature Review and Assessment of Implications' (2008) J Health Serv Res Policy 178,182; New Labour also advanced the argument that without the provision of patient choice, better-off patients will leave the NHS which will thus weaken the risk-pooling principle of the NHS; greater choice will therefore enhance social cohesion; see DA Barr and others, 'The Claim for Patient Choice and Equity' (2008) 34 J Med Ethics 271, 272 referring to the address by Alan Milburn, Secretary of State, to the NHS Chief Executives in 2003 <www.dd.gov.uk/en/News/Speeches/Speecheslist/DH_4000782> cf M Fotaki and others, *Patient Choice and the Organisation and Delivery of Health Services: Scoping Review.* Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO 2006) 118 stating that choice has not necessarily been introduced in order to keep middle-class individuals within the NHS. Risk-pooling, ie the sharing of risk across the whole population in solidarity, is not abandoned in the NHS where all people, even those who 'exit', still pay their taxes and thus contribute to the healthcare coffers. However, better-off patients can avail themselves of services that are difficult to obtain in the NHS.

[333] A Oliver, 'The English National Health Service: 1979–2005' [2005] Health Economics 575, 576.

1.5. Patient treatment choice in defence of the original settlement

Choice of treatment for the patient has been linked by governments in recent years with the notion of personalised healthcare in which patients receive a more tailored service.[334] It can be illustrated by the introduction of the concept of personal health budgets in the NHS under New Labour in 2009.[335] The current coalition government has continued the support for personal health budgets.[336]

1.5.1 The policy of personalised healthcare

Lord Darzi's report *High Quality Care for All* explains the concept of personalised healthcare under New Labour. The report states that people 'expect not just services that are there when they need them, and treat them how they want them to, but that they can influence and shape for themselves',[337] and 'want care that is personal to them',[338] concluding that 'a health service without freedom of choice is not personalised'.[339] *Liberating the NHS: Greater Choice and Control*, the White Paper of the current coalition government, states that personalised care planning is 'about engaging people in making choices about how they want to manage their care'; 'about setting personal goals and receiving appropriate support to achieve those goals as equal partners with health care professionals' and 'about treating a person

[334] C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204, 205; see eg Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008); Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009); Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010); Department of Health, *Liberating the NHS: Greater Choice and Control, a Consultation on Proposals* (HMSO 2010); Health and Social Care Act 2012.
[335] Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009).
[336] See eg Department of Health, *Liberating the NHS: Greater Choice and Control, a Consultation on Proposals* (HMSO 2010) 4.
[337] Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008) 26.
[338] ibid 33.
[339] ibid 38.

as a whole, recognising that there are other issues in addition to medical needs that can impact on a person's total health and wellbeing'.[340]

The personal health budgets in turn aimed to help ' people to get the services they need to achieve their health outcomes, by letting them take as much control over how money is spent on their care as is appropriate for them'.[341] Foreshadowed in *High Quality Care for All* under New Labour, personal health budgets, which are voluntary, were intended for patients with fairly stable and predictable conditions, such as patients with long-term chronic conditions.[342] According to *Personal Health Budgets: First Steps*, the personal health budgets were to allow patients to 'buy' a package of services in addition to the comprehensive primary medical services provided by GPs.[343] Likewise, the current coalition government's White Paper *Liberating the NHS: Greater Choice and Control* speaks of shared decision-making as being central to developing effective personalised care-plans for people with long-term conditions, with choice playing an 'important role in promoting equality and reducing inequalities', but also encouraging 'healthcare providers to tailor their services to what people want and to improve their quality and efficiency'.[344] Personal health budgets play a big part in choice and personalised care planning, and are 'an extension of personalised care planning' giving people 'more control over the money that is spent on their care'.[345]

1.5.2 Personalised healthcare and equity

The justification for these treatment choice policies by both the New Labour and the coalition governments was in terms of the original NHS settlement. Thus Lord Darzi's report stated that 'providing personalised care should also help us to reduce

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[340] Department of Health, *Liberating the NHS: Greater Choice and Control, a Consultation on Proposals* (HMSO 2010) 17.
[341] Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 9.
[342] Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008) 42.
[343] Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 28.
[344] Department of Health, *Liberating the NHS: Greater Choice and Control, a Consultation on Proposals* (HMSO 2010) 4.
[345] Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010) 55.

health inequalities, as the households with the lowest incomes are most likely to contain a member with a long-term condition'.[346] Likewise, New Labour's personal health budget scheme expressly underlined that the key principles of the NHS are to be upheld, specifically 'equality and tackling inequalities'.[347]

While the coalition government also explained these policies as linked to the value of equity, choice and personalisation of healthcare could not be separated from the issue of cost management in the NHS.[348] Efficiency, mentioned on twenty-five occasions in the White Paper *Equity and Excellence*, and costs, mentioned on thirty occasions, are a central theme. Efficiency in particular is a major driver: decision-making by patients about their own health and care, and patient choice, are amongst the changes intended to bring about a 'revolution in NHS efficiency'[349] while stating at the same time that '[the] intention is to secure excellence as well as equity'.[350]

Policy-makers thus utilise equity to make their policies palatable to the public, to construct a convincing narrative whether or not the value of equity can be satisfied.[351] Clearly, however, the issue of cost management in the NHS is one of the central political concerns; at the forefront of the political debate is still the question

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[346] Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008) 28 citing Department of Health, *Raising the Profile of long-term Conditions: A Compendium of Information* (HMSO 2008).

[347] Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 28.

[348] In contrast, New Labour's *Personal Health Budgets: First Steps* showed little commitment to efficiency with only one mention whereas the importance of the costs of personalised healthcare is recognised and mentioned on twenty-five occasions, see Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 18 which also refers to likely efficiency gains of personal health budgets with earlier intervention and prevention avoiding costly acute interventions. To be successful, personal health budgets will need to be cost-neutral in the long run, and the development of the care plan should have regard to using NHS resources in a reasonable and cost-effective manner, see Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 44. New Labour also emphasised that personal health budgets were to align with other guidance and policies and that approval for treatments that the NHS would not normally fund because they are not shown to be cost-effective will have to be obtained in the normal way from the PCT's exceptions committee, see Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 27; see also discussion in chapter 4.

[349] Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010) 45.

[350] ibid 8.

[351] See generally, C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204.

of how the rising costs of the NHS are to be managed.[352] The NHS which offers choice and personalised healthcare to the patient is a health service where patients are expected to be more active and more involved in their own care.[353] To this end, choice and personalised care have increasingly been linked with the theme of 'responsibilisation', or individuals taking responsibility for their lifestyle choices in relation to health. Affording patients choice makes patients therefore an unwitting tool in political manoeuvres of cost containment.[354] The shift to patients taking more control over the management of their health and their healthcare reduces their dependence on the NHS, and has the potential benefit of reducing the costs of publicly funded healthcare[355] while at the same time deepening the commitment to the value of solidarity.[356]

1.5.3 Personalised healthcare and solidarity

High Quality Care for All speaks of patients being enabled to self-care,[357] patients who are empowered by choice being more likely to take responsibility,[358] and people being encouraged to take responsibility for their own health throughout their lives.[359] Similarly in *Personal Health Budgets: First Steps* references are made to 'the

[352] K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313, 320; cf P Spicker, 'Personalisation Falls Short' (2012) British Journal of Social Work 1, 7 arguing, in the context of social care, that there are growing doubts that savings are to be made with personal health budgets so that other things being equal, personalisation will be no cheaper than the alternatives, and may be more expensive.
[353] C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204, 207.
[354] I Whiteman, 'The Fallacy of Choice in the Common Law and NHS Policy' (2011) Health Care Analysis, forthcoming <www.ncbi.nlm.nih.gov/pubmed/22109706> accessed February 2012 referring to K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313.
[355] K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313, 320.
[356] C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204, 213 referring to New Labour's avowed aim to use personalisation in order to deepen solidarity and equity within the NHS.
[357] Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (HMSO 2008) 40.
[358] ibid 33.
[359] ibid 319.

individual's own responsibility and accountability',[360] people having independence and choice but also responsibility,[361] people exercising their choice around support for self-care,[362] a culture shift in care planning starting from the assumption of self-care and control,[363] and support for self-care and self-management.[364] The current government's White Paper *Equity and Excellence: Liberating the NHS* and the consultation paper *Liberating the NHS: Greater Choice and Control* continues this theme of responsibilisation. *Equity and Excellence: Liberating the NHS* suggests that patients, in return for greater choice and control, should accept responsibility for the choices they make[365] and the need for increasing self-care.[366] *Liberating the NHS: Greater Choice and Control* addresses responsibilisation as patients taking more responsibility for their health and treatment choices[367] and building ownership of, and a shared responsibility for, managing their conditions, especially where lifestyle changes may be needed.[368] It also suggests that people living with long-term conditions should exercise choice around the self-care support they receive, so that they can manage their condition better and take more control over their health and wellbeing.[369] Patients are therefore positioned not only as conscious choosers of possible treatments but also as choosers of their lifestyle, and must therefore take greater responsibility for making healthy choices.[370] This emphasis on the individual to assume responsibility for the management of her own health and healthcare and making responsible choices is also encapsulated in the NHS Constitution: 'You

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[360] Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 29.
[361] ibid 38.
[362] ibid 30.
[363] ibid 29.
[364] ibid 11.
[365] Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010) 16.
[366] ibid 46.
[367] Department of Health, *Liberating the NHS: Greater Choice and Control, a Consultation on Proposals* (HMSO 2010) 23.
[368] ibid 4.
[369] ibid 26.
[370] I Greener, 'Towards a History of Choice in UK Health Policy' (2009) 31 Sociology of Health and Illness 309, 315, 322.

should recognise that you can make a significant contribution to your own, and your family's good health and well-being and take some personal responsibility for it.'[371]

Making patients become more active and take responsibility for their health, reducing acute episodes and hospital admissions of patients with long-term chronic conditions, rather than being resource intensive might lead to resource savings. Linking responsibilisation to the traditional values of the NHS, it is possible for policy-makers to interpret responsibilisation as a commitment to the value of solidarity by lessening the cost of publicly funded healthcare.

CAM and responsibilisation

Responsibilisation by making patients take more control over their health is a concept also underlying the holistic healthcare model of CAM. Unlike the biomedical model, the adoption of CAM with its emphasis on self-management and self-care might support a government strategy of responsibilisation, particularly of patients with chronic illnesses where CAM treatments have their place. Viewed in this light, personal health budgets affording patients this choice might therefore achieve their intended purpose: patients' reliance on CAM might lead to growing self-reliance in health matters and even help curtail the rising costs of healthcare in the field of chronic care. According to the report on the early experiences of budget holders, patients planned on using their healthcare budgets amongst other things on CAM, namely chiropractic, osteopathy and acupuncture but also therapies without any scientific basis[372] such as Reiki, massage, reflexology, aromatherapy and hydrotherapy.[373]

For policy-makers the ability to defend their patient treatment choice policies as consistent with the original settlement values helps to deflect the criticism of choice

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[371] Department of Health, *NHS Constitution for England* (HMSO 2012) 2b.
[372] House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000) 2.8 stating that therapies such as aromatherapy, massage and reflexology may, however, still help support patients in relieving stress and ameliorating side-effects of conventional therapies.
[373] Department of Health, Personal *Health Budgets: Early Experiences of Budget Holders, 4th Interim Report* (HMSO 2011) 13–15.

opponents who view these policies as a strategy for cost reduction by encouraging marketisation and possible privatisation.[374] Cost containment is clearly a major concern for the NHS[375] but to suggest that the underlying motivation is marketisation and possible privatisation of the NHS may be too narrow an explanation. The management of costs through policies of personalisation and concurrent responsibilisation need not necessarily be a policy concentrated *exclusively* on the extension of a market model. As has been argued, market mechanisms have not been the most efficient means to achieve cost savings in a publicly funded healthcare system.[376]

1.6. Patient treatment choice as a mechanism of destabilisation

Rather than being viewed as a coherent theme or narrative in developing a market model in healthcare, the policies of treatment choice, personalisation and responsibilisation ought to be viewed as *also* allowing different interpretations.[377] It is argued that policy-makers may be using these policies as a strategy of destabilisation, stirring up the entrenched institutional architecture of the NHS and encouraging reform.[378] This destabilisation strategy is clearly motivated to a large

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[374] See eg K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313, 320–21 who views personalised healthcare and responsibilisation as a political technique through which the government pursues its political objective of fiscal prudence. He further argues that the government can use responsibilisation to deflect criticism of its management of public expenditure on healthcare by shifting responsibility onto patients and the healthcare choices they have made. It is the electorate which decides about its healthcare services through its choices rather than the government, even though the opportunity to make such choices was provided by government policy. This patient empowerment (by patients exercising choice and taking control over their health) is used by government as a legitimating technique to embed the market-based model in the NHS.

[375] See eg A Roberts and others, *A Decade of Austerity? The Funding Pressures Facing the NHS from 2010/11 to 2021/22* (Nuffield Trust 2012).

[376] See also P Spicker, 'Personalisation Falls Short' (2012) British Journal of Social Work 1, 7.

[377] See generally C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204.

[378] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 249; W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 1 <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012.

extent by the need for fiscal austerity.[379] However, the motivation is certainly more complex and may include other intentions such as quality improvement, greater efficiency and responsiveness, and administrative modernisation[380] of the NHS. It may of course also have a populist motivation, based on increasing consumer satisfaction for reasons of electoral politics.[381] It is suggested that patients demanding increased access to CAM in the NHS may become the unwitting beneficiaries of this strategy of destabilisation.

Choice as 'a proxy for instability as a dynamic of system reform'[382] is the explanation for the patient treatment choice and personalisation in New Labour's policy documents.[383] From a textual analysis of these documents Needham, for example, concludes that personalisation is a narrative of disruption in response to organisational failure and is depicted in many texts as 'a "radical agenda" which will shake up the health service.'[384] As Needham states, a destabilisation agenda can be detected in the development of the personal health budgets.[385] In addition, she identifies that New Labour had a further 'clear agenda to encourage destabilisation'

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[379] W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 8 <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012; see also A Roberts and others, *A Decade of Austerity? The Funding Pressures Facing the NHS from 2010/11 to 2021/22* (Nuffield Trust 2012).

[380] See generally W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 7–9 referring to the motivations driving the agenda for more choice in the context of welfare reform in the EU generally <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012.

[381] ibid 8–9.

[382] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

[383] ibid 252 suggesting that choice is used with different meanings by New Labour from an effective policy mechanism to a market-like mechanism to a right.

[384] C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204, 210.

[385] ibid 212 although Needham states that the personal health budgets, intended to be cost-neutral, are a clear move from the concept of risk-pooling or the founding value of universality or solidarity. She refers to Department of Health, *Personal Health Budgets: First Steps* (HMSO 2009) 33 which states that 'opportunities for risk pooling are reduced' cf NHS Federation, Mental Health Network, 'Shaping Personal Health Budgets: a View from the Top' (2009) 6–13 disputing that the personal health budgets will compromise the founding values of the NHS but also admitting that they will increase costs <www.nhsconfed.org/Publications/Documents/Shaping_personal_health_budgets-a_view_from_the_top.pdf> accessed 1 September 2012.

with the encouragement of a diverse range of providers likely to lead to volatility with 'exit' by commissioners and also patients.[386]

The current government's patient treatment choice policies can likewise be regarded as a strategy of destabilisation albeit with a pronounced link to marketisation and privatisation mechanisms. The personal health budgets as part of the agenda for personalisation of healthcare are clearly a major system-level reform affecting the use of a wide range of services and support in the NHS.[387] The Health and Social Care Act 2012 enshrines the most extensive reorganisation of the structure of the English NHS to date, extending primary care provision to include 'any qualified provider'[388] intending to encourage 'fair and effective competition … [as] a means to give greater choice and control to patients to access high quality care'.[389] Necessarily a commissioning of services currently outside the scope of NHS provision is likely to encourage a reorganisation of the primary care sector and to lead to changed practices within the NHS.

CAM could become one of the beneficiaries of this governmental reform as the volatility in the primary care sector may in turn open up a greater space for CAM within the NHS.[390] Particularly in general practice, there has been a depreciation of the claims to expertise by orthodox medical practitioners,[391] with the changing relation between complementary and orthodox medicine becoming noticeable. More extensive incorporation of CAM in health service provision has also been aided by

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[386] C Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis' (2009) 3 Critical Policy Studies 204, 212.
[387] J Forder and others, *Evaluation of the Personal Health Budget Pilot Programme* Discussion Paper, 2840_2, PSSRU (University of Kent, Canterbury 2012) 124 <http://php.york.ac.uk/inst/spru/pubs/2331/> accessed 6 December 2012.
[388] Department of Health, *Operational Guidance to the NHS: Extending Patient Choice of Provider* (2011) <http://www.dh.gov.uk/publications> accessed 1 September 2012.
[389] Department of Health, *Health and Social Care Act Explained: Provider Regulation to Support Innovative and Efficient Services* <http://healthandcare.dh.gov.uk/act-factsheets/> accessed 6 December 2012.
[390] Department of Health, *Operational Guidance to the NHS: Extending Patient Choice of Provider*, 4 at <www.dh.gov.uk/publications> accessed 1 September 2012 referring to the potential inclusion of musculo-skeletal services into primary care subject to such providers meeting NHS requirements for service quality.
[391] See generally J Le Fanu, *The Rise and Fall of Modern Medicine* (2nd edn, Abacus 2011).

the change in the special relationship between the state and the medical profession since 1990 and the regulation of the professions of osteopaths and chiropractors under Acts of Parliament. At the same time, the current restructuring of expertise in general practice may be a populist move, particularly regarding patients suffering from intractable chronic conditions not amenable to cure by conventional medicine.[392] However, the greater incorporation of CAM in public health service provision may additionally have economic benefits because of the potentially lower cost of CAM and the possible reduced need for medical personnel.[393] Lastly, it may also allow a reformulation of the meaning of the 'comprehensiveness' of the NHS.

1.7. Conclusion

As has been discussed, the current policies of patient choice and patient treatment choice have been challenged on a number of levels. Choice as a proxy for competition and efficiency is criticised as a mechanism for the marketisation and privatisation of the NHS and, as such, anathema to the value of equity, but whether choice leads to efficiency gains is far from clear. Patient choice has further been challenged for its inequity-inducing effects as having a negative impact on geographical equity of access, on equity of access according to need and also in terms of patients with different levels of abilities and different levels of health literacy. However, policy-makers are able to justify their policies by relying on the traditional values of the NHS due to their ambiguity and haziness.

It has also been shown that more recently policy-makers have turned to the specific treatment choice policies of personalisation of healthcare and personal health budgets. These have been linked with the notion of responsibilisation, which also underlies CAM with its emphasis on self-management and self-care. Reduced dependency on the NHS through the responsibilisation of patients could simply be

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[392] S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 143; see also Department of Health, *Operational Guidance to the NHS: Extending Patient Choice of Provider* (2011) <www.dh.gov.uk/publications> accessed 1 September 2012.

[393] S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 143.

regarded as supporting the founding value of solidarity by reducing patient dependence on the NHS and containing costs. A patient choice of CAM could be advocated in this light. However, it has been argued that the patient choice policy may be motivated by different political objectives. Policy-makers may be using it as a mechanism to destabilise the institutional structure of the NHS encouraging change and reform. This volatility might reconfigure the space for CAM within the NHS and support the ongoing restructuring of the relations between orthodox and complementary medicine. Although it might be seen as a populist move by government it may also entail cost savings for the NHS.

These macro-level policy arguments, however, fail to take into account that in practice healthcare decisions are made at the micro-level, between patients and doctors, and at the meso-level between patients and PCTs, or in future CCGs. Thus, notwithstanding the macro-level policy of patient treatment choice[394] patients' choice of CAM may be compromised at the micro- and meso-levels, with patients' demand for CAM frustrated by GPs opposing the use of CAM by their patients[395] and PCTs only funding CAM in exceptional cases.[396] The interpretation of patient choice of treatment at the micro-level is discussed in the next chapter.

[394] Department of Health, *Government Response to the Science and Technology Committee Report, 'Evidence Check 2: Homeopathy'* (HMSO 2010) [9] referring to the overriding reason for NHS provision of homeopathy as providing patient choice rather than making provision dependent on the proven or unproven effectiveness of the treatment.
[395] See chapter 2.
[396] See chapter 4.

Chapter 2
Destabilising effects at the micro-level: Patient treatment choice in the courts and in the consulting room

2.1. Introduction

Policy-makers embrace the principle of patient treatment choice, linking it with the concept of patient responsibilisation, patient self-care and self-management. At the same time they subject the right to choice of treatment to the condition that treatment should be clinically 'appropriate'. Which treatment a patient will actually receive, however, is a micro-level decision reached at the level of the medical practitioner and the patient. In most cases there is no conflict between doctor and patient and the patient will receive her preferred treatment. With chronic conditions where patients are often experts about their symptoms and their responses to treatment, the decision may even be that complementary alternative therapy, amongst the various therapeutic options, is a suitable option.

This chapter discusses the less common situation of a conflict between doctor and patient, where the doctor deems the patient's desired choice of treatment inappropriate or offers a range of treatments which do not include the patient's preferred option. When conflict arises and the patient, relying on the political discourse of NHS choice and her right to choose, rejects the treatment or treatments offered by the doctor and demands her preferred choice, medical law becomes involved, and associated with it a concept as open to interpretation as the policy-makers' rhetoric: the concept of patient autonomy.

The chapter demonstrates that the rhetoric of autonomy employed by the courts in cases where the patient chooses to refuse or demand a specific treatment is in many cases of little benefit to the patient. In treatment refusal cases, conceptually based on the tort of battery and the lack of consent by the patient to bodily interference, the judicial conception of autonomy has tended towards a liberal interpretation as an absolute right to reject treatment. However, even in refusal cases, this rights

discourse is not unlimited but constrained by the judicial determination of a patient's deemed lack of capacity and inability to refuse consent.

The language of autonomy and rights has been transferred to claims for a specific treatment based on the common law[397] and as an infringement of the right to respect for one's private and family life under Article 8 of the European Convention on Human Rights (ECHR).[398] The decisions in cases such as *Burke*[399] and *Glass*[400] lead, however, to the conclusion that the judicial interpretation of patient choice is in conflict with the choice rhetoric of policy-makers at the macro-level and that patients cannot rely on the concept of autonomy in its liberal sense to justify a claim for a specific treatment, whether such treatment is orthodox or complementary alternative medicine (CAM) treatment.

It is argued, however, that litigation between patients and doctors involving claims of rights, while not achieving the desired objective of acknowledging patients' demand for specific treatment, also does not only affect the immediate parties to an action; the precedential dimensions of the common law extend beyond the individual case and such litigation is having a destabilising effect on healthcare practices and regulations. Doctors faced with patient demands will generally rely on the guidance of their regulatory body, the General Medical Council (GMC), which, while reflecting the decisions in the case law, goes much further than the common law to accommodate patients' preferences. To that extent at least, the more open attitude of many general practitioners (GPs) to consumer demand for CAM may well be an indirect outcome of the destabilising effect of patient litigation.

The chapter first gives a brief outline of different ethical conceptions of autonomy which are then compared with the inconsistent judicial interpretation of autonomy in treatment refusal cases and then proceeds to an analysis of the sparse case law on patient choice as a right to demand a specific treatment.

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[397] *R (Burke) v General Medical Council* [2004] EWHC 1879 (Admin) [Burke (Admin)].
[398] Incorporated into UK domestic law by the Human Rights Act 1998.
[399] *Burke* (Admin); and *R (Burke) v General Medical Council* [2005] EWCA Civ 1003 [*Burke* (Civil)].
[400] *Glass v UK* [2004] ECHR 102.

2.2. The many faces of autonomy

Since the publication in 1977 of Beauchamp and Childress's book, *Principles of Biomedical Ethics*,[401] the bioethical, and to some extent also the legal, discourse has been dominated by the principle of autonomy.[402] We live in the time of the triumph of autonomy in bioethics.[403] Not only medical ethics but also law today is dominated by the paradigm of the autonomy of the patient.[404] The mastery of patient autonomy is, however, not without its opponents amongst bioethicists as well as lawyers.[405] As has been suggested, one of the underlying problems with the concept of autonomy is that 'there are almost as many different conceptions as there are commentators writing on the subject'.[406] Gerald Dworkin, for example, equates the multi-faceted concept of autonomy with liberty, self-rule or sovereignty, freedom of will, dignity, individuality, independence, responsibility, self-knowledge, self-assertion, critical reflection, freedom from obligation, absence of external causation and knowledge of one's own interests.[407] These different conceptions of autonomy, developed in philosophy and bioethics, are based on the interpretations by libertarian, liberal, principled and relational autonomists. An outline of these interpretations of autonomy is sketched to highlight the approach taken by English judges when

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[401] T Beauchamp and J Childress, *Principles of Biomedical Ethics* (6th edn, OUP 2008).
[402] See eg M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397; J Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism' (2007) 15 Health Care Analysis 235; G Dworkin, *The Theory and Practice of Autonomy* (CUP 1997); C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009); A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009); S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010); J Montgomery, 'Law and the Demoralisation of Medicine' (2006) 26 LS 185; O O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002); K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007).
[403] C Schneider, *The Practice of Autonomy. Patients, Doctors, and Medical Decisions* (OUP 1998) xi.
[404] ibid 3; R Gillon, 'Ethics Needs Principles – Four Can Encompass the Rest – and Respect for Autonomy Should Be "First among Equals"' [2003] J Med Ethics 301, 310.
[405] M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397; C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009); A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009); S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010); K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007).
[406] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 10.
[407] G Dworkin, *The Theory and Practice of Autonomy* (CUP 1997) 6.

adjudicating on patients' healthcare choices whether in the area of refusal of treatment or demand for a specific treatment.

2.2.1 Libertarian and liberal autonomy

At a general level, *libertarian* autonomy is the right to self-determination supporting the idea of choice without presupposing any rational or moral decision-making by the person.[408] It is a view of autonomy that equates it with 'mere, sheer choice'.[409] The more meaningful *liberal* interpretation of autonomy limits individuals' demands on society.[410] Liberal autonomy is based on rational choosing offering more than sheer choice. The principal source for most conceptions of liberal or rational autonomy is John Stuart Mill.[411] Choices are made by exercise of the 'human faculties of perception, judgment, discriminate feeling, mental activity, and even moral preference'.[412] But reasoned choice is not unrestricted; the freedom of the individual to choose is not absolute. While the individual is not accountable to society as long as his actions only concern his own interests; if his actions are prejudicial to the interests of others or cause harm to others, he may be subjected to social or legal punishment.[413] Autonomy in either of these senses is concerned with the rights of individuals rather than with their obligations.

2.2.2 Relational autonomy

Relational autonomy rejects the notion of autonomy as the mere ability to make decisions. It acknowledges the inter-relationship of the person with society. Choices are considered as socially constructed and having consequences for the

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[408] eg R Nozick, *Anarchy, State and Utopia* (Arrowsmith 1974) 33, where he argues that the rights of the individual need to be respected, all individuals have separate lives so that no one may be sacrificed for others.
[409] O O'Neill, *Rethinking Informed Consent in Bioethics* (CUP 2007) 70.
[410] cf O O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002) 73, considering the libertarian and liberal views of autonomy ethically unsatisfactory, as they encourage ethically questionable forms of individualism.
[411] O O'Neill, 'Autonomy: the Emperor's New Clothes' (2003) 77 Proceedings of the Aristotelian Society, Supplementary Volumes 1, 3.
[412] JS Mill, *On Liberty and other Essays* (OUP 2008) 65.
[413] ibid 104.

community.[414] Sheila McLean argues that, while relational autonomy does not seek to deny the importance of decisional freedom, it tries to constrain the excessive selfishness of individualistic autonomy.[415] It also accepts that autonomous choices need to be made in response to obligations and responsibilities. Thus people are not merely decision-making machines, isolated from each other without obligations and responsibilities.[416] 'Relational autonomy recognises that no man is an island, but that we all exist in a network of relationships.'[417] Of course, such a model of autonomy does not reject the concept of autonomy as rational self-determination and rational choice, and has been criticised as a misunderstanding of liberal autonomy. Liberal autonomy does not negate that most individuals value their relationships and take them into account when arriving at their autonomous decisions.[418] Relational autonomists, however, see a moral component to the choices that the individual makes,[419] whether this moral component is part of the obligation to engage in a process of joint decision-making between patient and healthcare professional and reach a decision which is autonomous,[420] or private decisions are tested against their relational values. The choices of the individual are constrained because individuals do not tend to function in complete isolation from others.[421]

2.2.3 Principled autonomy

'*Principled* autonomy', to adopt O'Neill's term, is the conception of autonomy set out in Kant's writings. It grounds rights in obligations, based on Kant's concept of autonomy manifested in 'a life in which duties are met, in which there is respect for others and their rights, rather than in a life liberated from all bonds'.[422] It is moral

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[414] S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 21.
[415] ibid 23.
[416] ibid 24.
[417] C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009) 14.
[418] ibid.
[419] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 235.
[420] ibid 247.
[421] S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 23; E Jackson, *Medical Law: Text, Cases and Materials* (OUP 2010) 21.
[422] O O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002) 83.

autonomy[423] as opposed to personal or liberal autonomy, originating with the idea that morality consists of self-enacted principles. In this conception, autonomy is not about acting arbitrarily but is about creating an ethical world constructed on the basis of obligations rather than rights.[424] When speaking of rights, particularly in substantival ways, it is easy to imagine, according to O'Neill, that it is the individual making the rights claim against unspecified others or even at the world at large, whereas obligations of action or refraining from action have to be specified with specific claimants in mind.[425] Thus focussing on obligations takes the relationship between obligation bearer and rights holder as central.[426] In the context of a publicly funded, solidarity based healthcare system it may well be difficult not to consider obligations to others before considering an individual's choice.

The equivocal nature of the concept of autonomy in bioethics may lead to equally varied ways in which autonomy is used in law. Whichever of the various bioethical interpretations of autonomy is used by English judges, judicial interpretation ought to be consistent so that patients can predict whether their choices will be respected and will be enforceable. To determine whether patients have a legally enforceable choice, either when refusing treatment or demanding treatment such as CAM, it is necessary to analyse how judges translate autonomy into reality.

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[423] G Dworkin, *The Theory and Practice of Autonomy* (CUP 1997) 34; J Raz, *The Morality of Freedom* (OUP 1986) 370.

[424] O O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002) 78–81, where the author gives the following reasons for this: Firstly, obligations are structurally connected to rights. 'Any human right must have as its counterpart some obligation: A right that nobody is required to respect is simply not a right.' Secondly, obligations can be demonstrated to be connected to action. A right by itself is not effective but depends on individuals considering themselves under an obligation to respect the right. Thirdly, obligations are more readily distinguished and individuated than rights. Obligations are referred to when speaking of action. An obligation is an obligation to do or to refrain from doing something. In contrast, rights talk often uses substantival vocabulary such as in the 'right to healthcare' or 'right to life', with often highly inflated claims as to its meaning. To achieve clarity about rights it is usually helpful to use the vocabulary of action which tends to deploy the vocabulary of obligations. Lastly, an approach based on obligations is preferable because one can find better routes justifying obligations and hence rights than vice versa.

[425] ibid 82.

[426] ibid.

2.3. Autonomy in the courts

Autonomy has, as Brazier points out, belatedly acquired its own mastery in English law.[427] It has found a place in much of medical law but it is the law of consent that has been coined the 'heartlands of autonomy'.[428] It is the area where the results of judicial determinations include most references to autonomy as a reason for the decision.[429] The ruling orthodoxy links autonomy with the right to self-determination, the right to determine access to one's body.[430] To this extent at least, the definition of autonomy used by judges appears to come closest to the liberal or libertarian concept of autonomy. As Foster surmises, 'the highly edited samples of philosophical thinking to which judges are exposed will paint Millian autonomy as the all-trumping principle'.[431] The question is not only whether this judicial definition is unequivocal[432] but whether autonomy is interpreted as a *right* to autonomy and thus synonymous with the idea of patients' rights.[433] As Brazier

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[427] M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397, 401.
[428] C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009) 181.
[429] eg *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871; *Chester v Afshar* [2004] UKHL 41(HL); *Re B* (Adult: Refusal of medical treatment) [2002] EWHC 429 (Fam); *Re T* (Adult: Refusal of Treatment) [1992] 4 All ER 649, 665 [*Re T*].
[430] *Re F* (Mental Patient: Sterilisation) [1990] 2 AC 1, 73, where Lord Goff referred to autonomy as the libertarian principle of self-determination in the context of the tort of trespass, the unlawful touching of another's body without a lawful excuse; *Airedale NHS Trust v Bland* [1993] AC 789, 826, where Lord Hoffmann referred to the right to choose how one lives one's life in terms of individual autonomy or the right of self-determination. In *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, 882, Lord Scarman, in his dissenting opinion, referred to the right of self-determination as 'the patient's right to make his own decision which may be seen as a basic human right protected by the common law'. In *Re T,* 665, Butler-Sloss LJ stated: 'The right to determine what shall be done with one's own body is a fundamental right in our society. The concepts inherent in this right are the bedrock upon which the principles of self-determination and individual anatomy [sic] are based. Free individual choice in matters affecting this right should, in my opinion, be accorded very high priority.'
[431] C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009) 5.
[432] See eg J Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism' (2007) 15 Health Care Analysis 235, 2, stating that judges may simply pay lip service to autonomy and use the equivocal nature of the concept to achieve the outcome which they consider desirable in each case.
[433] K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 79.

suggests, autonomy has gradually become a claim to a right to health care, the health care of one's choice rather than simply the right to protect one's bodily integrity.[434]

Before turning to consider a possible right to a specific treatment it is necessary to examine the protection that the tort of battery, on which the right to refuse treatment is grounded, provides to the patient. It is the tort of battery or trespass which is the bodyguard of autonomy and protects bodily integrity.[435]

2.4. Autonomy and refusal of treatment

As has been suggested, the courts, rather than subordinating healthcare practice to legal control, have avoided developing hard rules which would curb the power of the medical profession, except in the area concerning the right of competent adults to refuse treatment.[436] Thus the touching of a person without his or her consent is *prima facie* unlawful and consent, in the context of treatment, has the legal function of making the touching of the patient by the doctor lawful.[437] Its ethical function is the respect of the patient's autonomy,[438] ensuring that unwanted treatment cannot be provided even if the doctor believes it to be in the interest of the patient.[439]

Where the patient has not given her consent to treatment, a doctor who intentionally commits an act causing direct contact with the patient's body is liable for the tort (and possibly the crime) of battery or trespass to the person.[440] Thus, in Judge

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[434] M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397, 400.
[435] ibid 399.
[436] J Montgomery, 'Law and the Demoralisation of Medicine' (2006) 2 LS 185, 204.
[437] E Jackson, *Medical Law: Text, Cases and Materials* (OUP 2010) 217; A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 191–92, where the author defines consent in this context as permission rather than as agreement, its meaning in the law of negligence; see also A Maclean, 'Magic, Myths, and Fairy Tales: Consent and the Relationship between Law and Ethics', in M Freeman (ed), *Law and Bioethics: Current Legal Issues, Volume 11* (1st edn, OUP 2008) 112, describing consent as the granting of permission to do something to the patient's body which would otherwise be unlawful.
[438] E Jackson, *Medical Law: Text, Cases and Materials* (OUP 2010) 217.
[439] S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 57.
[440] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 150; see also *Re W* (A Minor) (Medical Treatment) [1992] 4 All ER 627 (CA) 633 (Lord Donaldson MR) stating that the tort of battery entails active physical interference in the absence of consent with consent having the legal function 'to provide those concerned in the treatment with a defence … to a civil claim for damages for trespass to the person'.

Cardozo's well known statement in the US case of *Schloendorff v Society of New York Hospital*: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.'[441] As Lord Donaldson MR formulated the principle in English law:

> The law requires that an adult patient who is mentally and physically capable of exercising a choice must consent if medical treatment of him is to be lawful … Treating him without his consent or despite a refusal of consent will constitute the civil wrong of trespass to the person and may constitute a crime.[442]

The tort of battery entails active physical interference in the absence of consent. It does not extend to non-invasive treatment such as the prescription of therapeutic drugs, but includes the examination of the patient, taking blood, giving injections and surgery.[443] Further and major limitations for an action for battery are the definition of what counts as consent,[444] i.e. the need for the consent to be voluntary,[445] real[446] and given by a patient who has capacity.[447] Although the judicial

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[441] *Schloendorff v Society of New York Hospital* 105 NE 92 N Y (1914) 93.
[442] *Re T,* 653.
[443] cf A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 151, arguing that a doctor handing the patient tablets indicating the patient should take them may amount to battery.
[444] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 132.
[445] *Re T*, 662, where Lord Donaldson MR defined the voluntariness of consent: 'The real question in each such case is: does the patient really mean what he says or is he merely saying it for a quiet life, to satisfy someone else or because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself?'.
[446] *Chatterton v Gerson* [1981] All ER 257, 265, where Bristow J interpreted a real consent as follows: 'In my judgment once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real…'; see also E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 276, where the author argues that the problem with the type of consent needed in battery lies 'in working out when the information about a proposed treatment is so fundamental that, without it, consent must be regarded as ineffective'.
[447] *Re T*, 652–53 (Lord Donaldson): 'An adult patient who … suffers from no mental incapacity has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered … This right of choice is not limited to decisions

definition of each of these requirements poses a risk to the protection of a patient's autonomy, it is the definition of capacity which poses the greatest risk, which makes the qualified judicial support for patient autonomy apparent.[448]

As Teff argues, the focus of the law is on whether or not the battery has technically been committed and not on whether there has been a failure to respect the claimant's right to self-determination; the focus of the law is not on patient autonomy or choice

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which others might regard as sensible. It exists notwithstanding that the reasons for making the choice are rational, irrational, unknown or even non-existent.'

[448] K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 82, stating that this absolute right of choice, which does not depend on reasonableness of the patient's decision, appears to indicate the existence of unfettered patient choice in law, subject only to the patient possessing mental capacity. The problem lies, therefore, with the definition of capacity and the exceptions to it, see I Kennedy, *Treat Me Right* (OUP 1988) 178, where the author states that 'the commitment to autonomy represented by the requirement of consent … is respected by having a notion of incompetence; but it can also be undermined by it unless the criteria of incompetence are articulated as clearly as possible…'. See eg *St George's Healthcare NHS Trust v S, R v Collins, ex p S* [1999] Fam 26 (CA) where S refused consent to a Caesarean section. The surgery was carried out after she was detained under the Mental Health Act 1983 despite there being no evidence for a mental disorder except her apparently irrational refusal to consent to a Caesarean section. On appeal the unwanted surgery was held to be a trespass. *Re MB* (Caesarean Section) [1997] 2 FCR 541 where MB had refused to undergo a Caesarean section due to her needle phobia but the health authority obtained a declaration that it would be lawful to carry out such treatment as necessary, even if it involved using reasonable force as MB's needle phobia apparently rendered her temporarily incompetent; *NHS Trust v Ms T* [2004] EWCH 1279 (Fam) where Ms T who suffered from a borderline personality disorder had on a number of occasions self-harmed requiring blood transfusions. She subsequently drew up an advance directive with a solicitor which stated that she wished, if at any time in the future she experienced a mental health crisis, not to be given further blood transfusions. The document stated that she was fully aware that this refusal might lead her to die, but that at the time of writing she was mentally competent. A letter from her GP was attached to the document stating that Ms T understood the implications of not undergoing treatment. The document also referred to the reason for her refusal of blood transfusions, namely that she believed her blood was evil. Charles J held that her belief that her blood was evil was a misconception of reality pointing to a disorder of the mind or symptoms or evidence of incompetence. The judge did not restrict his finding of incompetence to the present situation but also found it to exist at the time when the advance directive was signed; cf *Re C* (Adult: Refusal of Treatment) [1994] 1 WLR 290 where C, a schizophrenic patient at Broadmoor, a secure hospital, was held to be competent to refuse the amputation of his gangrenous foot as he understood the 85-per cent risk of death as a consequence of retaining his limb; *Re B* (Adult: Refusal of medical treatment) [2002] EWHC 429 (Fam) where Ms B due to a haemorrhage was completely paralysed from the neck down and was wholly dependent on a ventilator. She decided that she did not want to continue living her life in such conditions and asked to have her ventilator switched off. Although several psychiatrists found her to have competence to make the decision to have her treatment discontinued, her treating clinicians refused to turn off the ventilator. B applied to the court for a declaration that her continued treatment was unlawful. Butler-Sloss P found her to have competence and that the continuing treatment against Ms B's expressed wishes constituted battery.

as such.[449] The emphasis on the technical aspects of battery is particularly apparent when the rules on capacity are being stretched to deprive some patients of their residual autonomy.[450] Generally, as long as the individual understands the nature of the decision and its risks, or is able to weigh up the information about the decision, she is deemed to have capacity and therefore has an absolute right of refusal, even if the choice leads to irreparable damage to health, or even to death.[451]

It may of course not always be easy to decide whether a patient has simply unwise or irrational views or is unable to understand the nature of the decision. Although judges claim not to be interested in the nature and rationality of a refusal decision, as Veitch states, they are very much concerned with these when assessing capacity.[452] The irrationality of a decision sometimes constitutes evidence of incompetence, particularly where refusal of treatment has serious consequences or a mental health issue is involved.[453] In a number of refusal cases it appears therefore that judges simply pay lip service to the autonomy of the patient, in the sense of liberal autonomy, while attempting to arrive at the 'right' outcome.[454] Some authors have suggested that autonomy in these cases was interpreted by the courts as principled autonomy,[455] or relational autonomy,[456] thus enabling the refusal of the patient to be disregarded without offending the concept of autonomy.

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[449] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 132.
[450] M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397, 398 referring to the decision in *R v Collins and Ashworth Hospital Authority, ex p Brady* [2000] Lloyds Rep Med 355; see note 76.
[451] *Re T*, 664 (Lord Donaldson).
[452] K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 85.
[453] E Jackson, *Medical Law: Text, Cases and Materials* (OUP 2010) 231.
[454] C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009) 94, stating 'the judges cannot bring themselves to say that they are no longer thoroughgoing autonomists, although what they actually do is justice, rather than autonomy'.
[455] J Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism' (2007) 15 Health Care Analysis 235, 253–54, arguing that judges appear to select the 'right' form of autonomy to reach the decision that sympathy requires. The author makes a distinction between current desire, best desire and ideal desire autonomy, with ideal desire coming closest to the Kantian or principled autonomy, the form of autonomy selected in the author's view in eg *NHS Trust v Ms T* [2004] EWCH 1279 (Fam); see also K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 96, interpreting *Re MB* (Caesarean Section) [1997] 2 FCR 541 as the use by the court of autonomy in its principled sense portraying the image of the responsible

Whether or not judges give different meanings to autonomy, since they are loathe to find doctors liable for the tort (and more so the crime) of battery, consent and its ethical correlate – autonomy – are better regarded as subsidiary to, or part of, the tort of battery rather than as free-standing elements. However, both consent and autonomy have taken on a life of their own in other areas of the law[457] and autonomy has been relied on in cases of demand for treatment, to which this chapter now turns.

2.5. Autonomy and demand for specific treatment

While non-consensual touching amounts to battery, and not respecting a competent patient's refusal of treatment would necessitate non-consensual touching, a *demand* for treatment is not an interference with one's bodily integrity. The right not to have one's bodily integrity infringed means that the doctor has a duty not to operate on or treat a patient without her consent[458] but it does not follow that the patient has a right to choose or demand a specific treatment. As Lord Donaldson MR stated obiter in *Re J*:

> No one can *dictate* the treatment to be given to the child, neither court, parents nor doctors. There are checks and balances. The doctors can recommend treatment A in preference to treatment B. They can also refuse to adopt treatment C on the grounds that it is medically contra-indicated or for some other reason is a treatment which they could not conscientiously

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pregnant woman who not only considers the consequences for herself of refusing a Caesarean section but prioritises the welfare of her baby.

[456] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 211, stressing the fragility of patient autonomy in the common law. He argues that judges' use of the relational form of autonomy allows a refusal to be disregarded where a 'socially valuable' life is at risk, eg *St George's Healthcare NHS Trust v S, R v Collins, ex p S* [1999] Fam 26 (CA) and to be accepted where, as in *Re C* (Adult: Refusal of Treatment) [1994] 1 WLR 290, 'it was of little social concern whether or not [C's] decision resulted in his death, which would have been of little, if any loss to the community'.

[457] eg in the area of information disclosure in the law of negligence, discussed in chapter 3; see also generally C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009).

[458] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 173.

> administer. The court or parents for their part can refuse to consent to treatment A or B or both, but cannot insist on treatment C.[459]

That an English court will not order a doctor to administer a specific treatment was also emphasised by Leggatt LJ in *Re J*, a later case, in a unanimous decision by the Court of Appeal:

> I can myself envisage no circumstances in which it would be right directly or indirectly to require a doctor to treat a patient in a way that was contrary to the doctor's professional judgment and duty to the patient. A court can give or withhold a consent or authority such as might be given or withheld by a patient or a child's parent. But no reported case has been cited to the court in which any judge in any jurisdiction has ever purported to order a doctor to treat a patient in a particular way contrary to the doctor's will until Waite J made his order in the present case.[460]

The courts in these cases defer to the judgment of doctors as knowing which treatment is medically indicated or is 'clinically appropriate'. The emphasis is not on the autonomy of the patient but rather on the doctor's clinical discretion or medical autonomy although medical autonomy cannot be unfettered.[461] Medical autonomy is underlined in English law by reference to the doctor having a duty to act in the patient's best interests.[462] Thus Lord Donaldson MR:

> The fundamental issue … is whether the court … should ever require a medical practitioner … to adopt a course of treatment which in the bona fide clinical judgment of the practitioner concerned is contra-indicated as not

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[459] *Re J* (A Minor) (Wardship: Medical Treatment) [1991] Fam 33 (CA) 41, repeated as part of the ratio by Lord Donaldson MR in *Re J* (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15 (CA) 27.
[460] *Re J* (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15 (CA) 31.
[461] D Price and others, 'Clinician Autonomy: Doctor's Orders?' (2007) 2 Public Policy & Law 124, 125, arguing that some reasons for non-treatment by a doctor, such as refusal of pain relief, would hold no moral weight regardless of deference to clinical judgment.
[462] *Airedale NHS Trust v Bland* [1993] AC 789, 819 (Butler-Sloss LJ).

> being in the best interests of the patient … I cannot at present conceive of any circumstances in which this would be other than an abuse of power as directly or indirectly requiring the practitioner to act contrary to the fundamental duty which he owes to his patient. This … is to treat the patient in accordance with his own best clinical judgment.[463]

This raises the question, however, whether under the guise of best interest courts are not authorising doctors to make choices that may reflect other than the patient's interests and which may be choices that go against the patient's expressed views.[464] It also raises the question whether the duty of the doctor to the patient and the exercise of her clinical judgment are not conflated in English law.[465]

Where does this leave the right to self-determination and the principle of autonomy giving patients the right of choice and not simply the right to refuse treatment? Is the right to choose not what patients are led to expect from the NHS choice policy? As Brazier argues, 'an emphasis on choice within the NHS increasingly results in clamour that patients must be given what they demand. Autonomy is extended to an argument that it creates an obligation on doctors to satisfy that choice.'[466] Autonomy is expressed in terms of rights, and denying patients their CAM treatment of choice in the NHS might arguably be considered unjust because other patients can afford to pay for it privately. After all, treating liberal autonomy with full theoretical rigour ought to include a right to choose one's treatment of choice.[467] Patients are led to expect that autonomy is the main value, and that autonomy puts them in control of their healthcare choices. Or is the patient's autonomy limited to giving consent to one or the other treatment on offer and to the question whether the consent was

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[463] *Re J* (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15 (CA) 26.
[464] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 143.
[465] Price and others, 'Clinician Autonomy: Doctor's Orders?' (2007) 2 Public Policy & Law 124, 127; H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 230–35; cf *Burke* (Admin) [88]–[97] (Munby J), judgment overturned on appeal.
[466] M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397, 414.
[467] Subject, of course, to resource allocation considerations, see chapter 4.

sufficiently informed?[468] The patient's right to demand a specific treatment came before the courts in the case of *Burke*[469] to which the chapter now turns.

2.5.1 The case of *Burke* and the common law

Mr Burke suffered from spino-cerebral ataxia, a degenerative brain condition which takes a very similar course to multiple sclerosis and had confined him to a wheelchair. At some time in the future he would be likely to require artificial nutrition and hydration (ANH) while still mentally competent. He would later become totally immobilised, dependent on others and unable to communicate but still retaining full cognitive faculties even at the end stage of his illness. He would therefore still be aware of the pain and distress due to malnutrition and dehydration should ANH be withdrawn. Mr Burke was concerned about the GMC guidance for doctors on withholding and withdrawing treatments that may prolong life, issued in 2002.[470] He believed that a doctor might interpret these guidelines as authorising withdrawal of ANH despite the express wishes of a patient to continue receiving such treatment as long as possible. Mr Burke wanted to receive ANH until he died from natural causes.

Munby J, in a lengthy judgment in the High Court, granted the declaration of the unlawfulness of some of the paragraphs of the guidelines sought by Mr Burke. The judgment is remarkable because of Munby J's emphasis on the right to autonomy as the right to self-determination. He appeared to deduce this free-standing right of autonomy from cases involving the torts of battery and negligence.[471] As Foster concludes: 'The ratio of Munby J's judgment can be said to be: Autonomy trumps all.'[472] Rather than speaking of the duty by the doctor to provide treatment, Munby J

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[468] See discussion in chapter 3.
[469] *Burke* (Admin).
[470] General Medical Council, *Withholding and Withdrawing Life-Prolonging Treatment: Good Practice and Decision-Making* (GMC 2002) [81].
[471] eg *Re T*; *Re MB* (Caesarean Section)[1997] 2 FCR 541; *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871.
[472] C Foster, '*Burke*: A Tale of Unhappy Endings' (2005) 4 JPIL 293, 295; cf J Montgomery, 'The Legitimacy of Medical Law' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 8, where he argues that liberal autonomy does not work for patients' demands for

emphasised the patient's rights under the common law,[473] noting that the duty the doctor owes is a duty to act in the best interests of what *the patient* considers to be his best interests:

> The duty to care is, in principle a duty to provide that treatment which is in the best interest of the patient … Doctors can properly claim expertise on medical matters; but they can claim no special expertise on the many non-medical matters which go to form the basis of any decision as to what is in the patient's best interests. Medical opinion, however eminent, can never be determinative of what is in a patient's best interest. *In the final analysis it is for the patient, if competent, to determine what is in his own best interests*.[474] (My italics)

Best interests: the patient's or the doctor's view?

As Biggs points out, Munby J's discussion of the relationship between the concepts of autonomy, best interests and patients' demands was held to be unhelpful by the Court of Appeal.[475] Not surprisingly, Munby J's advocacy in the High Court was overturned. Lord Phillips MR criticised the use of 'best interests' in the context of the competent patient.[476] Using best interests in this way would suggest that 'treating a patient in the manner that doctors consider to be in his best interests may be at odds with the patient's wishes'.[477] Rather, the 'best interests' test was of most use when considering the duty owed to an incompetent patient, and easiest to apply

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particular treatment since to require a doctor to act moves the question from being purely self-regarding to having an impact on others or becoming a public matter.

[473] Following the dicta of Sir Bingham in *Frenchay Healthcare NHS Trust v S* [1994] 1 WLR 601, 609, who reserved to the court the ultimate power to review the doctor's decision; cf Munby J's judgment concerning Article 8 of the European Convention of Human Rights (ECHR) is discussed below.

[474] *Burke* (Admin).

[475] H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 230.

[476] See also *Re F* (Mental Patient: Sterilisation) [1990] 2 AC 1, 52 (Lord Bridge) holding that, in the case of the patient being incompetent, a doctor who gives treatment in the absence of consent in the best interests of the patient is not liable for trespass to the person; see also now the Mental Capacity Act 2005 s 1(5) requiring treatment of a patient lacking capacity to be in his best interest.

[477] *Burke* (Civil) [30].

where the relevant interests were medical.[478] All the same, the doctor owes a duty to her patient to administer such treatment as is in the patient's best interests,[479] a duty generally determined by the *Bolam* test,[480] meaning that the doctor should provide treatment regarded as proper by a 'responsible body of medical opinion'.[481] Munby J's distinction of *Bolam* and best interests, with the former only concerning clinical perspectives, was rejected by Lord Phillips.[482] His Lordship, therefore, in Miola's words, effectively '*re-Bolamised*' the concept of best interests.[483]

Clinically indicated treatment

To dispel the GMC's concern that doctors might be forced to accede to a patient's demand for a specific treatment, Lord Phillips offered the following guidance:

> The doctor, exercising his professional judgment, decides what treatment options are clinically indicated, (i.e. will provide overall clinical benefit) for his patient … Where the patient wants a treatment which the doctor has not offered to him the doctor will, no doubt, discuss that form of treatment with him (assuming that it is a form of treatment known to him) but if the doctor concludes that this treatment is not *clinically indicated* he is not required (i.e. he is under no legal obligation) to provide it to the patient.[484]

Although *Burke* dealt with the specific facts of a patient demanding ANH at the end of life, the Court of Appeal's dicta are as all-encompassing as those of Munby J. It appears that whether or not a treatment is clinically indicated is decided by the doctor who is entitled to exercise her therapeutic discretion in making her assessment of the best interests of a competent patient.[485] Thus, a doctor can

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[478] ibid [29].
[479] ibid [27].
[480] *Bolam v Friern Hospital Management Committee* [1957] WLR 582, 586 (McNair J).
[481] H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 233.
[482] *Burke* (Civil) [28].
[483] J Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (OUP 2007) 178.
[484] *Burke* (Civil) [50] (Lord Phillips MR).
[485] H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 234.

legitimately decide that certain treatments are not in the best interests of a patient and need not be made available. For example, she may not consider CAM to be in the best interests of a patient and therefore need not offer such a treatment.

Both the expression 'clinically indicated' and the *Bolamisation* of the best interests of the patient are arguably open to criticism.[486] Not only does 'the doctor's judgment about a treatment being "clinically indicated" import an old-fashioned doctor-knows-best paternalism into the process of medical decision-making',[487] but a *Bolamised* best interests test also ensures that, despite policy-makers' rhetoric, common law leaves patients' treatment choice firmly within the medical profession's discretion. It also amounts to a disregard of patient autonomy in its liberal interpretation.

While Munby J did not consider the specific case before him as involving a question of resource allocation, it may be possible to imply a principled interpretation of autonomy in the Court of Appeal's decision, especially if one considers the effect of a patient's right to demand treatment on other patients. In the context of refusal cases Veitch, for example, argues that as blind faith in medical paternalism is no longer considered acceptable by the judiciary, the use of principled autonomy captures the idea of responsible choice. Thus 'principled autonomy … offers the possibility of stressing the importance of patients being able to decide for themselves, while … allowing for an investigation into the extent to which they have met various indeterminate standards of obligation and responsibility.'[488] In this view, the request for a specific treatment might not be responsible and the expression of independent reason, and the rejection of a right to choose can thus be defended by turning to patients' and doctors' obligations and duties. Clinical discretion as to what treatment is appropriate is determined by the doctor's obligation of doing the 'right'

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[486] See eg R Veatch, *Patient, Heal Thyself: How the 'New Medicine' Puts the Patient in Charge* (OUP 2009) 71, arguing that the notion of a treatment being medically indicated is built on a model of medical decision-making which is not tenable: 'it is an attempt to clothe value judgments in medicine with a garb of medical objectivity'.
[487] C Foster, '*Burke*: A Tale of Unhappy Endings' (2005) 4 JPIL 293, 298.
[488] K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 102–03.

thing for her patient. Patients' moral and legal obligations are then seen as deciding in favour of one of the offered treatment options, including no treatment.[489]

While the common law and reliance on principled autonomy does little to accommodate patients' rights, Mr Burke also claimed his right to autonomy under human rights principles, which will be discussed next.

2.5.2 Human rights law and patient autonomy

The central role of human rights in healthcare is of relatively recent origin in the English courts as, traditionally, healthcare disputes between doctor and patient regarding the provision and quality of healthcare were considered primarily as an aspect of tort law.[490] This is not to say that there have not been criticisms of the regulation of the practice of medicine by resort to the law of battery and also the law of negligence.[491] For Kennedy, for example, medical law should be approached in terms of human rights, the rights of patients.[492] To analyse the law wholly in terms of duties rather than rights ignores the imbalance or disequilibrium of power which exists in the doctor-patient relationship.[493] The role of patients' rights is to set permissible limits to the exercise of the doctor's powers.[494] As Montgomery points out, the view of medical law as human rights law can be contrasted with the non-interventionist approach by judges presenting little threat to the autonomy of the professions and the hegemony of medicine, although things have begun to change.[495] Extra-judicially, judges themselves have acknowledged that the courts had treated

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[489] J Montgomery, 'The Legitimacy of Medical Law' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 14, arguing that the resulting partnership between doctor and patient is that of moral equals with neither taking precedence over the other.
[490] E Wicks, *Human Rights and Healthcare* (Hart 2007) 37.
[491] See eg E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006).
[492] I Kennedy, *Treat Me Right* (OUP 1988) 386–87; I Kennedy and A Grubb, *Medical Law* (3rd edn, OUP 2000) 3; see also K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 123, commenting on Munby J's judgment in *Burke* as coming close to characterising medical law as a subset of human rights law.
[493] I Kennedy, *Treat Me Right* (OUP 1988) 387.
[494] ibid.
[495] J Montgomery, 'Law and the Demoralisation of Medicine' (2006) 26 LS 185, 201.

the medical profession with excessive deference[496] but there is some evidence for a change occurring due an increasing awareness of patients' rights. As Lord Woolf has stated:

> Like it or not, we have moved from a society which was primarily concerned with the duty individuals owed to society to one which is concerned primarily with the rights of the individual … The move to a rights-based society has fundamentally changed the behaviour of the courts.[497]

Likewise, extrajudicially, Lord Irvine has stressed that the courts had become more interventionist and more reluctant to allow the medical profession dictate to them.[498] The ECHR, to which the Human Rights Act 1998 (HRA) gives effect, may encourage the courts to focus more on the patient's rights and 'this may prove not entirely compatible with what doctors have traditionally seen as their duties'.[499]

Human rights law advocates a prioritisation of individual autonomy and rights in English medical law.[500] Although Mason and Laurie express concern that embracing the language and values of the human rights discourse may lead to 'overly-individualistic notions of autonomy' in the area of medical law, they accept that autonomy, although not specifically mentioned in the ECHR, forms part of the rights enjoying protection particularly as part of the respect due to private and family life under Article 8(1).[501] The Article provides: 'Everyone has the right to respect for his

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[496] Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) 9 Med L Rev 1, 1; also Lord Irvine of Lairg, 'The Patient, the Doctor, their Lawyers and the Judge: Rights and Duties' (1999) Med L Rev 255; Brooke LJ, 'Patients, Doctors and the Law (1963–2003): a Few Reflections' (2004) 72 Medico-Legal Journal 17.

[497] Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) Med L Rev 1, 2.

[498] Lord Irvine of Lairg, 'The Patient, the Doctor, Their Lawyers and the Judge: Rights and Duties' (1999) Med L Rev 255, 267, where his Lordship referred critically to the *Bolam* test; see also chapter 3..

[499] ibid.

[500] E Wicks, *Human Rights and Healthcare* (Hart 2007) 3.

[501] JK Mason and GT Laurie, *Mason and McCall Smith's Law and Medical Ethics* (8th edn, OUP 2011) 46–47.

private and family life, his home and his correspondence'.[502] It has been interpreted as including 'a right to determine for ourselves how we live our lives, free from state interference, including in respect of what medical treatment we receive'.[503] The European Court of Human Rights (ECtHR) has confirmed this interpretation in the case of *Pretty*:[504]

> Although no previous case has established as such any right to self-determination as being contained in Article 8 of the Convention, the Court considers that the notion of personal autonomy is an important principle underlying the interpretation of the guarantees.[505]

The right protected is not just a right against arbitrary interference by the state and public authorities such as NHS Trusts and their staff, but extends to positive obligations by the state to protect those rights against positive or negative infringement by others.[506] Rather than the negative aspect of autonomy as freedom from interference when making a choice between available options, this could be interpreted as the positive aspect of a patient's autonomy which requires that unavailable choices are actively provided.[507] Does Article 8 of the ECHR allow such a positive right to demand medical treatment which would make established English legal precedent inconsistent with the Convention? Prior to the coming into force of the Human Rights Act 1998, Buxton LJ had denied that Article 8 did provide such a right in *R v North West Lancashire Health Authority, ex p A, D and G*,[508] a case that

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[502] This right is qualified by Article 8(2) and has to be balanced against societal interests; see, eg E Wicks, *Human Rights and Healthcare* (Hart 2007) 12.
[503] ibid 12.
[504] *Pretty v United Kingdom* (2002) 35 EHRR 1, where the Court found Article 8 rights to be engaged but interference justified under Article 8(2).
[505] ibid [61].
[506] J Marshall, 'A Right to Personal Autonomy at the European Court of Human Right' (2008) EHRLR 337, 346, discussing the meaning of Article 8 in the context of the jurisprudence of the ECtHR regarding transsexual identity.
[507] A Maclean, 'The Human Rights Act 1998 and the Individual's Right to Treatment' [2000] Medical L Intl 245, 245.
[508] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA), a case discussed in more detail in the chapter on judicial review.

involved the provision of gender reassignment surgery and the question of resource allocation.[509]

Before turning to the case of *Burke* and the right to demand treatment under the Convention, we note that the right to demand treatment had already come before the court in Strasbourg in the case of *Glass v UK*.[510]

Glass and the right to treatment under Article 8 ECHR

David Glass, a twelve-year-old boy who was severely mentally and physically disabled, had been readmitted to hospital on several occasions with respiratory failure. The doctors considered his condition terminal and further intensive care inappropriate, prescribing diamorphine to relieve the child's pain and suffering and putting a Do Not Resuscitate (DNR) order in the child's notes, the latter without the mother's knowledge. On discovering the order, the child's mother and family objected, disagreeing with the doctor's diagnosis and the administration of diamorphine as a palliative measure which they believed to amount to euthanasia. They demanded that life-preserving treatment should be provided[511] but diamorphine was administered all the same. A fracas broke out between the family and doctors during which the mother resuscitated her son and the doctors were injured. Despite the doctors' pessimistic prognosis the child's condition improved and he was again discharged from hospital. The mother's application for judicial review was rejected at first instance, a decision which was confirmed on appeal. 'Judicial review was too blunt a tool' for the sensitive issues in such a case but that, in the case of a serious dispute between parents and doctors, the matter could be

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[509] A Maclean, 'A Crossing of the Rubicon on the Human Rights Ferry' (2001) 64 MLR 775, 776 arguing that the case is indicative of a restrictive approach to the interpretation of the HRA 1998; regarding resource allocation, see C Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Hart 2009) 130, arguing that right to treatment will be affected by the scarcity of resources, and A Maclean, 'The Human Rights Act 1998 and the Individual's Right to Treatment' [2000] Medical L Intl 245, 249 arguing that the right to demand treatment is qualified by the government's obligation to ensure the economic well being of the country or the protection of health of others under Article (2); for a discussion of the issue of resource allocation see chapter 4.

[510] *Glass v UK* [2004] ECHR 102.

[511] *R v Portsmouth Hospitals NHS Trust, ex p Glass* (1999) 50 BMLR 269, 276.

brought before the court to decide on the best interests of the child.[512] As Maclean points out, this case is a good example of the judiciary subordinating patients' rights to doctors' clinical judgment.[513]

The child's mother then applied to the ECtHR which held that the child's Article 8 rights had been infringed and the hospital trust ought to have sought a court judgment to resolve the disagreement. Pecuniary damages were awarded but the case did not conclude that doctors needed to provide treatment against their clinical judgment. Contrary to expectations in 2000,[514] and although the Convention and therefore the HRA 1998 entail a different approach from the common law to determining the obligations of doctors and the rights of patients, the case does not suggest that patients can enforce a right to demand treatment.

Burke and Article 8 ECHR

As the case of *Burke* turned on the right to life-saving treatment, it also implicated several Convention Articles, including Article 2 (the right to life) and Article 3 (the right not to be subjected to inhuman or degrading treatment).[515] It is, however, Article 8, the right to respect for private life, which is the issue. For Munby J, Article 8 enshrined the principle of autonomy, expressed in *Burke* through an advance directive. As Munby J stated:

> The personal autonomy protected by Article 8 means that in principle it is for the competent patient, and not his doctor, to decide what treatment *should or should not* be given in order to achieve what *the patient* believes conduces to his dignity and in order to avoid what *the patient* would find distressing.[516]

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[512] ibid 281–82.
[513] A Maclean 'The Human Rights Act 1998 and the Individual's Right to Treatment' (2000) Medical L Intl 245, 253.
[514] ibid.
[515] *Burke* (Admin) [178] (Munby J) stating that any positive obligations of the state under Article 2 or Article 3 cease where they come into conflict with the patient's right of autonomy under Article 8; see generally D Gurnham, 'Losing the Wood for the Trees: *Burke* and the Court of Appeal' (2006) Med L Rev 253, 256.
[516] *Burke* (Admin) [178].

Leaving aside considerations of Articles 2 and 3 ECHR, what this statement amounts to is that a competent patient has a right to demand treatment, that the patient's wishes are determinative. The interpretation of autonomy in its negative sense, bound up with consent and the tort of battery making the touching of the patient by the doctor unlawful, is changed to one which entitles the patient to determine her own treatment.

As Mason and Laurie point out, Munby J speaks 'of the "absolute nature" of the right to respect for autonomy and self-determination'.[517] For some commentators this interpretation has far-reaching consequences and conflates autonomy with egotistical hedonism:[518] it means that what the patient wants is what the patient gets.[519] Other commentators are concerned that it might lead to doctors having to provide contra-indicated or inappropriate treatments according to the patient's demands.[520] Munby J's judgment can therefore be regarded 'as an assault on medical discretion',[521] 'a thinly veiled attempt to empower patients',[522] widening the treatment choices available to Mr Burke, including the opportunity to have his own opinion about his best interests respected. In this light, the HRA 1998 has changed the relationship between doctor and patient to a less paternalistic and more rights-based one in accordance with the principle of individual autonomy.[523] This could cause the problem that doctors may feel pressurised to treat contrary to their clinical judgment. As Gurnham points out,[524] Munby J avoids this by suggesting that a doctor need not treat a patient against her professional judgment but this did not

[517] JK Mason and G Laurie, 'Personal Autonomy and the Right to Treatment: A Note on *R (on the application of Burke) v General Medical Council*' (2005) 9 Edin LR 123, 130.
[518] ibid 134.
[519] ibid 130; M Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) CLJ 397, 414.
[520] H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 235, citing eg A Samanta and J Samanta, 'End of Life Decisions' (2005) 331 BMJ 1284.
[521] ibid 234.
[522] K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 125.
[523] D Gurnham, 'Losing the Wood for the Trees: *Burke* and the Court of Appeal' (2006) Med L Rev 253, 259.
[524] ibid.

exonerate the doctor from her duty to find another doctor who will provide the treatment.[525]

The Court of Appeal, in a single judgment by Lord Phillips MR, was scathing in its criticism of Munby J's judgment.[526] It rejected the rights based arguments preferring to express the case as one of doctors' duties rather than patients' rights.[527] In the words of his Lordship:

> Autonomy and right of self-determination do not entitle the patient to insist on receiving a particular medical treatment regardless of the nature of the treatment. Insofar as a doctor has a legal obligation to provide treatment this cannot be founded simply upon the fact that the patient demands it. The source of the duty lies elsewhere.[528]

The case of course turned on ANH rather than on treatment generally, and must be read in light of this. Thus 'for a doctor deliberately to interrupt life-prolonging treatment in the face of the competent patient's expressed wish to be kept alive, with the intention of thereby terminating the patient's life, would leave the doctor with no answer to a charge of murder.'[529] In the realm of medical treatment, whether or not at the end of life, the right the patient possesses is the right to refuse the treatment options which the doctor considers appropriate. As stated, albeit obiter, by his Lordship, 'in truth the right to choose is no more than a reflection of the fact that it is

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[525] *Burke* (Admin) [191] with Munby J distinguishing *Re J* (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15 (CA) – which decided that a doctor could not be compelled to treat a patient against his clinical judgment – on the grounds that it predates the HRA 1998; cf JK Mason and G Laurie,' Personal Autonomy and the Right to Treatment: A note on *R (on the application of Burke) v General Medical Council'* (2005) 9 Edin LR 123, 135 arguing that *Re J* [1993] may have also been distinguished because it was heard in the Family Division rather than being a case of judicial review in the Administrative Court.

[526] *Burke* (Civil) [24] describing it as largely irrelevant since much of the judgment concerned incompetent patients rather than competent patients in Mr Burke's position; H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 228.

[527] *Burke* (Civil) [31]; see also D Gurnham, 'Losing the Wood for the Trees: *Burke* and the Court of Appeal' (2006) Med L Rev 253, 259; C Foster, '*Burke*: A Tale of Unhappy Endings' (2005) 4 JPIL 293, 296.

[528] *Burke* (Civil) [31].

[529] ibid [34].

the doctor's duty to provide a treatment that he considers to be in the interests of the patient and that the patient is prepared to accept'.[530] Thus the Court of Appeal acknowledged that the doctor's view of the patient's best interests is paramount when determining which treatments should be made available, and patients cannot demand a treatment not recommended by the doctor.[531] As Gurnham concludes, the fundamental difference in approach between the two judgments is Munby J's invocation of Convention rights and the enforceability of patients' rights and the Court of Appeal's reliance on the medical profession's self-regulation.[532]

Although human rights law could be 'a powerful tool in controlling medical power', it would not be difficult to conclude that the ECHR, as interpreted by the English courts, may be quite friendly to paternalistic medicine.[533] English courts have been reluctant to make major changes, stressing the need for a restrained judicial role.[534] Although Article 8 includes a right to autonomy in its liberal sense, Maclean argues that judicial concern regarding clinical integrity (and also resource allocation) underlies the caution of the courts in interpreting human rights provisions.[535] The rights under the HRA 1998 are interpreted 'to ensure that they are compatible with the common law rather than by adapting the common law to concord with those rights.'[536] Thus, Veitch concludes that deploying human rights to defend common law rules and principles necessarily diminishes the ability of the patient to use the human rights discourse as a means to criticise the content of the law.[537] The rejection of a more proactive approach by the judiciary in favour of patients,[538] and the

[530] ibid [51].
[531] H Biggs, '"Taking Account of the Views of the Patient", but only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 238.
[532] D Gurnham, 'Losing the Wood for the Trees: *Burke* and the Court of Appeal' (2006) Med L Rev253, 263.
[533] J Montgomery, 'The Legitimacy of Medical Law' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 10.
[534] ibid; K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 114.
[535] A Maclean, 'A Crossing of the Rubicon on the Human Rights Ferry' (2001) 64 MLR 775, 793.
[536] ibid; see eg *Burke* (Civil) [39].
[537] K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 122.
[538] ibid 126.

reassertion of a limited judicial function witnessed in the Court of Appeal in *Burke*, will leave treatment decisions litigated in the courts in the hands of the doctor.

Litigation between patients and doctors involving claims of rights to specific treatment may not be successful in the courts but, as Sabel and Simon argue, tort litigation does not simply operate as a mechanism of dispute resolution.[539] The precedential dimensions of common law adjudication extend beyond the parties to the action and shape the backdrop of general rules which regulate social interaction.[540] Thus, in areas such as tort law, the common law has a tendency 'to destabilise congealed social practices'.[541] In the healthcare arena, private law litigation regarding patients' rights to demand a specific treatment similarly has potentially destabilising effects on healthcare regulation and practices. These effects extend to the guidance provided by the regulatory body of the medical profession, the General Medical Council (GMC). This guidance has undergone frequent revisions and, despite the outcome of the decision in *Burke*,[542] has generally been a step ahead of the common law requirements.[543] It is to the GMC guidance the chapter turns next.

2.6. GMC guidance

Not only can professional guidance be more specific, but also doctors are more likely to be influenced by the professional guidance than by case law emerging from the courts.[544] Doctors, rather than looking to the law, will look to the GMC for

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[539] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1057.
[540] ibid.
[541] ibid.
[542] *Burke* (Admin).
[543] See eg General Medical Council, *Good Medical Practice* (GMC 2001); General Medical Council, *Good Medical Practice* (GMC 2006); General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998); General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC, 2008); see J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106, making this point in the context of information disclosure; M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 130; E Jackson, *Medical Law: Text, Cases and Materials* (OUP 2010) 212–14.
[544] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 106; S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 95.

guidance on managing patients' expectations regarding choice of treatment. In turn the GMC's role as regulator of the medical profession includes the power to advise its members on standards of professional performance and medical ethics.[545] Although not legally binding, GMC guidance functions as a benchmark for considering doctors' fitness to practise and a basis of appraisal for NHS doctors.[546] In this light, the remainder of this chapter considers to what extent, in response to the destabilising effects of common law litigation, the GMC has encouraged a model of patient-centred care prioritising patients' wishes concerning their treatment over and above what the common law demands.

2.6.1 Guidance on consent and on end of life care

Patients and Doctors Making Decisions Together,[547] the guidance on consent published after the decision in *Burke*, appears to restrict the patient's role in treatment decision-making where there is conflict with the doctor to the role endorsed by the Court of Appeal in *Burke*,[548] namely that of having veto power only. Thus, if patients ask for a treatment that the doctor considers would not be of overall benefit to them, the doctor should discuss the issues and explore the reason for their request but the doctor does not have to provide the treatment. He should explain any other options available, including the option to seek a second opinion.[549] The guidance, a revision of *Seeking Patients' Consent*,[550] seems clear about its interpretation of the Court of Appeal's judgment in *Burke*:

> For the purposes of this guidance, the key point is the Court of Appeal's opinion that doctors are under no legal or ethical obligation to agree to the

[545] Medical Act 1983, s 35.
[546] Medical Act 1983, part III A; see generally J Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (OUP 2007) 5–6.
[547] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008).
[548] *Burke* (Civil) [50]–[51].
[549] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008) [5d].
[550] General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998).

> patient's request for treatment if they consider the treatment is not in the patient's best interests.[551]

Likewise, the GMC's *Treatment and Care Towards the End of Life*,[552] replacing the 2002 guidance *Withholding and Withdrawing Life-Prolonging Treatment*,[553] the subject matter of *Burke*, repeats that the doctor does not have to provide the treatment requested by the patient if he considers the treatment clinically appropriate.[554] The endorsement of the Court of Appeal's judgment in *Burke* leaves the GMC open to a charge of endorsing medical paternalism as it does not appear to change the legal position regarding treatment requests.

Although a reaffirmation of the limits to patients' rights, the GMC guidance, however, places the emphasis on the decision-making process.[555] Thus the emphasis in *Consent: Patients and Doctors Making Decisions Together* is on joint decision-making.[556] Although much of the guidance involves the provision of information, the principles stated at the beginning of the guidance require doctors to listen to patients and respect their views and to discuss with patients what their diagnosis, prognosis, treatment and care involve.[557] The key principle in Part 1 of the guidance is partnership, which is emphasised in Part 2 by the reference to the need for the exchange of information between doctor and patient as central to good decision-making.[558] As Miola stresses, the guidance and the requirement to engage with the

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[551] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008) 39.
[552] General Medical Council, *Withholding and Withdrawing Life-Prolonging Treatment: Good Practice and Decision-making* (GMC 2002).
[553] General Medical Council, *Treatment and Care towards the End of Life: Good Practice in Decision-making* (GMC 2010).
[554] ibid [14d].
[555] A Maclean, 'From *Sidaway* to *Pearce* and Beyond: Is the Legal Regulation of Consent Any Better Following a Quarter of a Century of Judicial Scrutiny?' (2012) 20 Med L Rev 108, 127, stressing that the law focuses more on the outcome of the process than the process itself.
[556] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008).
[557] ibid [2a-b]; see also J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106.
[558] J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106; E Jackson, *Medical Law: Text, Cases and Materials* (OUP 2010) 213.

patient goes generally beyond what English law demands of doctors.[559] It also goes further than *Seeking Patients' Consent* which placed greater reliance on the patient's trust to achieve a successful doctor-patient relationship.[560] Even if the patient's rights do not extend to demanding a specific treatment, the current guidance places more demands on the doctor regarding the decision-making process, focusing on whether the doctor has engaged the patient in a partnership approach to decision-making. Thus: 'whatever the context in which medical decisions are made, you must work in partnership with your patients to ensure good care. In doing so, you must … respect patients' decisions.'[561]

Similarly, *Treatment and Care Towards the End of Life* places considerable weight on the involvement of the patient and their family and carers in the treatment decisions that may arise at the end of life, the very issues that concerned Mr *Burke*.[562] While the guidance reiterates its interpretation of the legal position that a doctor need not provide 'clinically inappropriate' treatment to the patient[563] the guidance is overall more nuanced, giving prominence to the decision-making process and joint discussions between doctor and patient and the patient's family and carers. Regarding advance care planning, for example, the guidance states: 'If a patient in your care has a condition that will impair their capacity as it progresses … you should encourage them to think about what they might want for themselves

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[559] J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106.
[560] General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998) 1; J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106; cf S Fovargue and J Miola, 'One Step Forward, Two Steps Back? The GMC, the Common Law and "Informed" Consent' (2010) 36 J Med Ethics 494, where the authors criticise the 2008 GMC guidance regarding its minimal encouragement for shared decision-making despite the title of the guidance.
[561] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008) [2e].
[562] General Medical Council, *Treatment and Care towards the End of Life: Good Practice in Decision-Making* (GMC 2010); see also I Whiteman, 'The Fallacy of Choice in the Common Law and NHS Policy' (2011) Health Care Analysis, forthcoming <www.ncbi.nlm.nih.gov/pubmed/22109706> accessed 5 April 2012.
[563] GMC, *Treatment and Care towards the End of Life: Good Practice in Decision-Making* (GMC 2010) [14d].

should this happen … Your discussions should cover … the patient's wishes, preferences or fears in relation to their future treatment and care …'[564]

2.6.2 Good medical practice

In 2006, comprehensive changes had already been made to the GMC's core professional guidance with the publication of *Good Medical Practice*.[565] Both *Consent: Patients and Doctors Making Decisions Together* (2008) and *Treatment and Care Towards the End of Life* (2010) reaffirm in their preliminaries the duties of doctors as laid down in the new core guidance. The most significant change is the move towards promoting a doctor-patient partnership, a recurring theme in the document.[566] *Good Medical Practice* stresses the duties of a doctor as being; to work in partnership with the patient, to respect patients' right to reach decisions with the doctor about their treatment and care[567] and to support patients in caring for themselves to improve and maintain their health.[568] Most importantly, regarding patients with chronic, long-term conditions, the doctor's role is to promote patient self-care and self-management, to encourage patients to take an interest in their health and to take action to improve and maintain it.[569] In *Good Medical Practice* the GMC states: 'To fulfil your role in the doctor-patient partnership you must … support patients in caring for themselves to improve and maintain their health … [and] encourage patients who have knowledge about their condition to use this when they are making decisions about their care.'[570]

Although reference to self-care and self-management and the encouragement of decision-making is omitted from the 2008 guidance *Consent: Patients and Doctors Making Decisions Together*, the guidance set out in *Good Medical Practice* as the

[564] ibid [53].
[565] General Medical Council, *Good Medical Practice* (GMC 2006).
[566] ibid 15; see also M Brazier and E Cave, *Medicine, Patients and the Law* (5th edn, Penguin 2011) 16.
[567] General Medical Council, *Good Medical Practice* (GMC 2006) [22].
[568] ibid [4].
[569] ibid [21].
[570] ibid [21e-f].

current core professional guidance is not obsolete.[571] The later GMC document is particularly relevant in the context of acute or life-threatening situations where patients are reliant on the expertise of the doctor providing the therapy options and it makes sense for patients only to have veto power of healthcare decisions. However, in situations where patients can claim superior knowledge and expertise, such as patients with long-term chronic illness, it makes much less sense. As Holm suggests, the 'expert patient' movement has shown that patients with chronic diseases can become experts in the management of their own particular illness and key decision-makers in the treatment process.[572] These patients often know more about the corner of healthcare that is relevant to them than the healthcare professionals, and can acquire the knowledge and skills to make decisions independently.[573] The doctor will still know more about medicine than the patient, but in the concrete situation this is often irrelevant. It is the patient who is the most expert regarding her condition in the specific context, and it is the patient who manages her illness on a daily basis and can make the general claim that the decision is about her life.[574] It is the expert patient who may also be aware of the effects and side-effects of orthodox treatment regimens and may ask for complementary and alternative treatment options.[575] In Teff's words, non-medical dimensions of ill health can be vital to an assessment of what constitutes good medical treatment in a particular case, and only the patient can be fully aware of the impact that an illness is having on her life.[576] Thus the optimum choice of treatment is not necessarily that deemed to be the most appropriate one, or in the patient's best interests, by the doctor.

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[571] A revised guidance of *Good Medical Practice* will be published in 2013.
[572] S Holm, 'Final Responsibility for Treatment Choice: The Proper Role of Medical Doctors?' [2011] Health Expectations 201, 206; see also generally Department of Health, *The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century* (Department of Health 2000).
[573] S Holm, 'Final Responsibility for Treatment Choice: The Proper Role of Medical Doctors?' [2011] Health Expectations 201, 206; S Watt, 'Clinical Decision-making in the Context of Chronic Illness' [2000] Health Expectations 6, 13.
[574] S Holm, 'Final Responsibility for Treatment Choice: The Proper Role of Medical Doctors?' [2011] Health Expectations 201, 207.
[575] S Watt, 'Clinical Decision-Making in the Context of Chronic Illness' [2000] Health Expectations 6, 6.
[576] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 123.

The *Good Medical Practice* guidance takes cognisance of this and of the large patient group affected by a long-term chronic condition, estimated by the Department of Health in 2000 to number 17.5 million people in the United Kingdom.[577] Clearly, in most cases patient and doctor will agree on the treatment. As Biggs points out, the vast majority of medical decisions are reached by mutual agreement between doctor and patient, even when there is initial disagreement.[578] The support of patients' self-care and self-management advocated in *Good Medical Practice* is reminiscent of government policy of patient responsibilisation. It also, at least in part, explains why GPs, who are the most familiar with long-term chronic conditions,[579] have yielded to some extent to consumer demand for CAM perceived as suitable for these conditions.

2.7. Conclusion

On the basis of the interpretation of autonomy in the common law and human rights law, there is no legal right to compel a doctor to act against her clinical judgment to provide a treatment that he regards as contrary to the patient's best interests.[580] Unless included in the treatment options offered by the doctor, the choice of a different treatment such as CAM cannot be insisted on by the patient, however expert she may be in managing her condition and taking responsibility for her health. The situation of the patient at the micro-level is therefore in stark contrast to the rhetoric of choice heard from policy-makers at the macro-level. Munby J's judgment in *Burke* was appealed by the medical profession, through the GMC, seeking to protect therapeutic discretion. They feared that the case amounted to a 'Draconian

[577] Department of Health, *The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century* (Department of Health 2000) 15.
[578] H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees– *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 238.
[579] S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 98.
[580] *Re J* (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15 (CA) 26; see also H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 234.

restriction of the exercise of the doctors' professional skills'.[581] The subsequent rejection of the judgment at first instance by the Court of Appeal handed the GMC a resounding victory.[582]

However, as has been argued, litigation by patients in the area of refusal of or demand for treatment, although rarely successful, exerts destabilising effects on healthcare practices and regulation. It has led to a debate on patients' rights and a change in the attitude of the medical profession as represented by the comprehensive changes to GMC guidance in the recent past. The partnership model in decision-making advocated by the guidance helps explain why the expert patient affected by long-term chronic illness may in many cases be the key decision-maker regarding her treatment. It also helps explain to some extent at least why some GPs react more positively to patient demand for CAM.

The next chapter considers the treatment options which need to be disclosed by the doctor to enable a patient to arrive at an informed choice of treatment; contrasting an action in the tort of negligence for lack of 'informed consent', which requires more detailed information, with the minimalist information requirements for 'real consent' to rule out an action for battery.

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[581] H Biggs, '"Taking Account of the Views of the Patient", But only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*' (2007) 19 Child & Fam LQ 225, 235 citing R Gillon, 'Why the GMC Is Right to Appeal over Life Prolonging Treatment' (2004) 329 BMJ 810, 811.
[582] J Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (OUP 2007) 177.

Chapter 3
Destabilising effects at the micro-level: Patients' rights to information about treatment alternatives in tort and under GMC guidance

3.1. Introduction

Policy-makers do not only support the concept of patient treatment choice but recognise that information is vital for the patient's ability to choose.[583] The NHS Constitution speaks of the patient's right to information.[584] *Equity and Excellence: Liberating the NHS*, the White Paper published by the then new coalition government in 2010, refers to an information revolution: 'We will put patients at the heart of the NHS, through an information revolution and greater choice and control … Patients will have access to the information they want, to make choices about their care.'[585] The White Paper consultation document *Liberating the NHS: an Information Revolution* speaks of good health care being dependent on good information as the basis for genuine shared decision-making between doctor and patient and that 'without the right information, support and infrastructure being in place the vision of informed, empowered patients making choices over the things that matter to them is unlikely to be achieved'.[586] As a good example of a genuine dialogue between doctor and patient about treatment options the document points to the long-term conditions model, which includes a personalised care planning discussion, focused on the needs and wants of the patient[587] which is also the area where CAM may be located.

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[583] Department of Health, *Equity and Excellence: Liberating the NHS* (HMSO 2010); Department of Health, *Liberating the NHS: an Information Revolution* (HMSO 2010); see also Health and Social Care Act 2012.

[584] Department of Health, *NHS Constitution for England* (HMSO 2009) 2 which states: '*You have the right* (my italics) to be given information about your proposed treatment in advance, including any significant risks and any alternative treatments which may be available, and the risks involved in doing nothing.'

[585] Department of Health, *Equity and Excellence: Liberating the NHS*, 3.

[586] Department of Health, *Liberating the NHS: An Information Revolution*, 2–3.

[587] ibid [2.18]–[2.19].

This chapter discusses the protection of the rights of the patient to information about proposed treatments and the alternatives, including CAM treatment options, in English tort law. It discusses whether tort law recognises the right of the patient to medical disclosure of treatment information, often referred to as the doctrine of informed consent, covered by the tort of trespass or battery and the tort of negligence.[588] It contrasts the definitional limitations of the tort of trespass with the limitations of the tort of negligence regarding the patient's interest in information about treatment options and their attendant benefits and risks. Specifically it analyses the extent to which either is concerned with the patient's right to self-determination, comparing the patient's right to a minimum of information necessary for *real consent* under the law of trespass[589] with the requirement for more extensive information disclosure under the law of negligence, covering the disclosure of available treatment options.[590] However, the law of negligence, rather than being defined in terms of patients' rights, is defined in terms of doctors' duties[591] and any remaining illusion of patients' informational rights is further destroyed in that the adequacy of the information provided is assessed in accordance with the professional standard underpinned by the *Bolam* test[592] test or some modified version of the *Bolam* test.[593]

Because of these definitional limitations of both torts regarding patients' rights to information and the additional relatively rigorous application of the causation principles in the tort of negligence patients have rarely been successful in informed

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[588] G Robertson, 'Informed Consent to Medical Treatment' [1981] LQR 102, 104–105 contrasting *Salgo v Leland Stanford Jr University Board of Trustees* 317 P 2d 170 Cal App (1957) where the court spoke of lack of informed consent rendering the doctor liable for trespass, with the court in *Natanson v Kline* 350 P 2d 1093 Kan (1960) considering lack of informed consent due to non-disclosure as constituting negligence.

[589] *Chatterton v Gerson* [1981] All ER 257; M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 172.

[590] *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871; *Pearce v United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA).

[591] *Chatterton v Gerson* [1981] All ER 257; P Skegg, 'English Medical Law and "Informed Consent": an Antipodean Assessment and Alternative' (1999) 7 Med L Rev 7 135, 139.

[592] *Bolam v Friern Hospital Management Committee* [1957] WLR 582.

[593] See eg *Pearce v United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA).

consent claims.[594] However, it is argued that informed consent litigation has had considerable destabilising effects on healthcare practices,[595] evidenced by the frequent revisions to the professional guidance with regard to this issue by the GMC.[596] GMC guidance expects a much higher standard of information disclosure from doctors than does tort law, and rather than being guided by the minimal requirements of the law doctors are looking to the standards set by the GMC regarding the exchange of information with their patients.[597] These higher standards may well include a discussion of CAM treatment options particularly with patients with long-term, chronic conditions.[598]

The chapter begins by briefly analysing the problem of the definition of the doctrine of informed consent and then proceeds to contrast the doctrine under both torts as a means to protect the patient's right to adequate information to enable her to choose her preferred treatment.

3.2. The definition of 'informed consent'

Although a doctor can only provide treatment to a patient who has first given her informed consent to the treatment,[599] the phrase has been described as 'apt to

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[594] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 123; G Robertson, 'Informed Consent Ten Years Later: The Impact of *Reibl v Hughes*' (1991) 70 CBR 423; G Robertson, 'Informed Consent 20 Years Later?' (2003) Health L J, special edn, 153.

[595] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1056–1958 where the authors assert that litigation and adjudication in tort law have polycentric effects; these effects are not self-contained between the parties to the action but have a destabilising effect.

[596] eg General Medical Council, *Good Medical Practice* (GMC 1995); (GMC 1998); (GMC 2001); (GMC 2006); General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998); General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008); see also J Miola, *Medical Ethics and Medical Law, A Symbiotic Relationship* (OUP 2007) 79–82.

[597] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 286; M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 133; cf how this higher standard of the GMC guidance may in turn impact on the legal standard, see eg M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 133; J Miola, *Medical Ethics and Medical Law, A Symbiotic Relationship* (OUP 2007) 85.

[598] See eg General Medical Council, *Good Medical Practice* (GMC 2006) [21f] which encourages the involvement of the expert patient in treatment decisions.

[599] J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 76.

mislead'[600] and 'vague and ambiguous'.[601] This is because the word 'informed' does not describe the *type* or *amount* of information required. Consent necessarily requires a minimum of information so that one knows what one is consenting to.[602] Skegg suggests that it is unfortunate that the term 'sufficiently informed consent' did not become common, as it would have made users aware that the issue concerned how informed one had to be for the purpose in question.[603] However, even the addition of 'sufficiently' or 'adequately' to the word 'informed' as a qualification of consent may simply emphasise the need for consent, rather than suggest a distinct concept. Nevertheless, as Brazier already argued over twenty years ago, the phrase 'informed consent' is too well established to be dislodged: it acts as a useful shorthand for who ultimately takes the decision on the patient's medical treatment, and how much information the patient should be given.[604]

The doctrine of informed consent, as imported from the United States,[605] appeared to conflate trespass and negligence.[606] The concept in English law, however, distinguishes between an action in medical trespass and an action in negligence,

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[600] See eg P Skegg, 'English Medical Law and "Informed Consent": an Antipodean Assessment and Alternative' (1999) 7 Med L Rev 7 135, 136 citing I Kennedy and A Grubb (eds), *Principles of Medical Law* (OUP 1998) [3.86].

[601] A Maclean, 'The Doctrine of Informed Consent: Does It Exist and Has It Crossed the Atlantic?' (2004) 24 LS 386, 387.

[602] ibid; C Foster, *Choosing Life, Choosing Death* (Hart 2009) 98.

[603] P Skegg, 'English Medical Law and "Informed Consent": an Antipodean Assessment and Alternative' (1999) 7 Med L Rev 7 135, 138.

[604] M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 172.

[605] JK Mason and GT Laurie, *Mason and McCall Smith's Law and Medical Ethics* (8th edn, OUP 2011) 106.

[606] The US case *Salgo v Leland Stanford Jr University Board of Trustees* 317 P 2d 170 Cal App (1957), which is said to have given birth to the doctrine, was decided on the basis that lack of a patient's informed consent to a procedure vitiated consent and therefore rendered the doctor liable in trespass. Only three years later, the US case of *Natanson v Kline* 350 P 2d 1093 Kan (1960) in contrast decided that a lack of risk disclosure, rather than vitiating consent, amounted to a breach of the doctor's duty of care and therefore constituted negligence; see also G Robertson, 'Informed Consent to Medical Treatment' (1981) LQR 102, 104–105; C Foster, *Choosing Life, Choosing Death* (Hart 2009) 100–101.

based on the difference between the quantity and type of information which is not communicated.[607]

3.3. The right to information under the tort of trespass

A doctor is liable under the tort of trespass or battery when the medical treatment has been given without any valid or 'real' consent by the patient.[608] Only the patient's consent to the treatment will absolve the doctor from liability for unlawful touching: the patient must know the nature of the treatment she is consenting to.[609] If the patient consents to a procedure which is wholly different from the one performed, there is no real consent.[610] However, all that is required for the consent to be real is that the patient has been informed in broad terms of the nature of the procedure.[611]

A commitment to patient autonomy in its liberal sense would require that *all material* information necessary to reach a decision and give consent ought to be provided. As Teff argues, insisting that patients have 'consented' to procedures without knowing what they entail is over-literal and artificial.[612] Consent after all seeks to transfer some power to the patient in the areas affecting her self-

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[607] *Chatterton v Gerson* [1981] All ER 257.

[608] *Chatterton v Gerson* [1981] All ER 257, 265 where Bristow J gave as an example of lack of real consent the case of a boy admitted to hospital for a tonsillectomy but who, due to an administrative error, was in fact circumcised; see also J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 78; E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 276.

[609] *Re F* (Mental Patient: Sterilisation) [1990] 2 AC 1, 12 (Lord Donaldson): 'in the absence of consent all, or almost all, medical treatment and all surgical treatment of an adult is unlawful, however beneficial such treatment might be.'.

[610] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 276; A Maclean, 'The Doctrine of Informed Consent: Does it Exist and has it Crossed the Atlantic?' (2004) 24 LS 386, 393 arguing that the informational requirements of 'real consent' are relatively easy to satisfy; see eg *Davis v Barking, Havering and Brentwood Health Authority* [1993] 4 Med LR 85 where consent to a general anaesthetic was sufficient to constitute consent to a caudal block, a form of epidural anaesthetic, although its purpose was analgesic rather than anaesthetic; M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 110.

[611] *Chatterton v Gerson* [1981] All ER 257, 265 (Bristow J).

[612] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 134.

determination.[613] However, for consent to be valid under the law of trespass it is unnecessary for all material information to be disclosed.[614]

Needless to say it is difficult to see how consent which is uninformed and given in ignorance of relevant risks and alternatives can be deemed valid.[615] The distinction between the nature of the procedure and serious risks associated with it appears unduly restrictive in a situation where trust plays a major role.[616] Similarly, how can a patient be said to give valid consent when aware of the nature of one treatment but not of the alternative treatments and their possibly lower risks? The definition of medical trespass should not be restricted to non-disclosure of the nature or type of treatment 'to the extent of excluding almost completely the protection under the tort of the patient's right of self-determination'.[617]

Instead Tan, for example, suggests a test for trespass based on the *degree* of information rather than the *type* of information not disclosed, which requires a greater failure of medical advice to be established than in medical negligence to render a treatment non-consensual.[618] Information of alternative treatment options ought to be included in the information necessary for a valid consent. After all, in order to arrive at an informed choice, the patient needs to be able to weigh up the small benefits of one treatment option with the high risks but greater benefits of another treatment. Where the patient's choice, for example, is between angiography

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[613] I Kennedy, *Treat Me Right* (OUP 1988) 178.
[614] *Sidaway v Bethlem Royal Hospital Governors and others* [1984] 1 All ER 1018 (CA) 1026 (Dunn LJ): 'The … argument was that unless the patient's consent to the operation was a fully informed consent the performance of the operation would constitute a battery on the patient by the surgeon. This is not the law of England. If there is consent to the nature of the act, then there is no trespass to the person.'
[615] R Crisp, 'Medical Negligence, Assault, Informed Consent and Autonomy' (1990) JL & Soc'y 77 asking how consent to surgery with a high risk of partial paralysis can be valid as not going to the *nature of the treatment* if the patient was not informed of this high risk?
[616] K Tan, 'Failure of Medical Advice: Trespass or Negligence' (1987) 7 LS 149; H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 134.
[617] K Tan, 'Failure of Medical Advice: Trespass or Negligence' (1987) 7 LS 149, 164; H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 135.
[618] K Tan, 'Failure of Medical Advice: Trespass or Negligence' (1987) 7 LS 149, 162; M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 179.

and an MRI scan, with their different risk profiles, why should the lack of information not have vitiated consent for the purposes of trespass?[619]

Likewise, if failure to disclose risks and alternatives were considered to vitiate consent then the fact that a reasonable doctor would not have disclosed them would not absolve him from liability.[620] Since trespass is based on the patient's integrity, Tan argues that it is for the *reasonable* patient to give consent to the medical procedure. The test for sufficiency of knowledge would therefore be the reasonable patient test.[621] This more generous interpretation of the prerequisites for consent under the tort of trespass would contribute to redressing some of the imbalance favouring medical paternalism.[622]

Leaving aside the problem of the minimalist definition of real consent, as Teff states, the tort of trespass

> is not fundamentally concerned to ask 'what must be done in order to safeguard, to the fullest extent possible, the right of the patient as an autonomous person to choose between courses of action affecting him or her?' Its focus is on whether the doctor's conduct satisfies the constituent elements of the tort of battery.[623]

The tort of trespass requires that the patient has been physically touched by the doctor when there has been no consent to such contact. There has to be direct contact with the patient, however trivial, to amount to sufficient force.[624] The requirement of physical contact makes an action in trespass unsuitable for the prescription of drugs,

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[619] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB), a case which turned on these facts but was brought as an action in negligence.
[620] G Robertson, 'Informed Consent to Medical Treatment' [1981] LQR 102, 124.
[621] K Tan, 'Failure of Medical Advice: Trespass or Negligence' (1987) 7 LS 149, 162 where he discounts the subjective patient test to determine consent, since all patients who sue their doctors would claim they never consented.
[622] ibid 165.
[623] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 136.
[624] M Jones, *Medical Negligence* (Sweet & Maxwell 2008) [6-004]; A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 192.

so trespass would not offer a remedy to a patient who complained of lack of disclosure of side-effects.[625] Medical treatment usually involves physical contact: for example, an injection or the taking of blood or any manipulation of the patient would be sufficient for this purpose. However, as Tan argues, the law could overcome the problem of the lack of directness of the administration of a drug in the case of failure of advice of serious drug side-effects by 'regarding the causal sequence as sufficiently direct for the purpose of developing medical trespass in order to protect the patient's right of self-determination'.[626]

Thus although an action in trespass would have the potential to enforce the patient's right to information, the courts have been reluctant to find any scope for liability for trespass in the medical context.[627] This is regrettable since the fact that there is no need to prove harm under the tort protects the patient's right to self-determination. As Jackson points out, in a successful action for medical trespass it is the harm to the patient's dignity which is being compensated: 'It is the violation of the patient's right to make an informed choice which is being compensated' rather than the materialisation of some remote risk.[628]

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[625] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 275; S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 71; M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 180.

[626] K Tan, 'Failure of Medical Advice: Trespass or Negligence' (1987) 7 LS 149, 163.

[627] The reason for this reluctance may be that courts do not wish to label doctors as criminals, since generally doctors will treat their patients with the aim of benefiting them rather than with criminal intent, see I Kennedy, *Treat Me Right* (OUP 1988) 181; M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987)7 LS 169, 180; S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish, 2010) 152; H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 137; A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 192; G Robertson, 'Informed Consent to Medical Treatment' (1981) LQR 102, 124. It may also be because judicial policy may be influenced by the fear of expanding the liability of the medical profession especially as the patient does not have to prove damage, see H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 137; A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 192.

[628] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 275; M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 179; I Kennedy, *Treat Me Right* (OUP 1988) 181.

The aggrieved patient who has received inadequate information is therefore more likely to look towards the tort of negligence for a remedy. The chapter now turns to consider what protection the law of negligence affords the patient's right to information.

3.4. Informational rights and duties under the tort of negligence

The difficulty with informed consent in negligence arises from the fact that the doctor's duty to provide the patient with treatment information, and the need to obtain the patient's consent, are closely connected but often confused.[629] The focus is on the doctor's behaviour rather than on the patient's autonomy, as the law of negligence emphasises the doctor's duty rather than the consent of the patient, but the doctor's behaviour is ultimately subject to judicial control and scrutiny.[630] If it were different, would the law not insist on the understanding of the patient? Information is central for consent, and to have made an informed decision suggests a process of deliberation based on understanding.[631] However, there is no insistence in negligence on the understanding of the patient.[632] While the question ought to be whether the patient has adequate *understanding* of the relative advantages and disadvantages of the proposed treatment and alternative treatment options to enable him to make an informed decision, English case law does not bear this out.[633]

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[629] P Skegg, 'English Medical Law and "Informed Consent": an Antipodean Assessment and Alternative' (1999) 7 Med L Rev 135, 139.

[630] S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 72; see also G Robertson, 'Informed Consent to Medical Treatment' [1981] LQR 102, 126 arguing that it is judicial policy rather than the patient's right to determine his own medical treatment which determines the doctrine of 'informed consent' in the law of negligence.

[631] H Teff, Reasonable *Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 196; S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 72.

[632] Informed consent in negligence elides the distinction between a patient who has been merely notified rather than one who comprehends, the essentially one-way process of imparting information and the kind of dialogue that truly equips the patient to work towards a decision, see H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 196.

[633] *Al Hamwi v Johnston and Another* [2005] All ER (D) 278 [69] where Simon J stated: 'to ensure that the information given to the patient is understood … is to place too onerous an obligation on the clinician … Clinicians should take reasonable and appropriate steps to satisfy themselves that the patient has understood the information which has been provided; but the obligation does not extend to ensuring that the patient has understood'; J Miola, 'Commentary – Autonomy Rued ok? *Al*

To make disclosure of information part of the doctor's general duty of care is to shift the emphasis away from a patient-centred right of autonomy.[634] Thus the patient's right to be informed of treatment risks is a derivative right dependent on the doctor's duty of care rather than the individual's right to self-determination.[635] However, although a rights-based approach to informed consent in negligence is therefore problematic, the vocabulary of autonomy or the right to self-determination have on occasion been deployed, arguably misleadingly, by the courts in England under the aegis of negligence.[636]

Rather, any residual 'rights' the patient may have to satisfy her informational requirements depend on the judicial approach to the duty of information disclosure.[637] The difficulty in specifying how much information about benefits and risks of a treatment and its alternatives ought to be disclosed to patients is reflected

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Hamwi v Johnston and Another' (2006) Med L Rev 108; A Maclean, 'Magic, Myths, and Fairy Tales: Consent and the Relationship between Law and Ethics', in M Freeman (ed), *Law and Bioethics: Current Legal Issues. Volume 11* (1st edn, OUP 2008) 126; H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 197; E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 281; cf M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 118 commenting on the difficulty of communicating medical information to the patient which cannot be a duty to give medical seminar but only to give an explanation which is reasonably comprehensible to a layman; see also M Brazier , 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 177.

[634] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP 2009) 193; E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 275.

[635] ibid; see also J Jackson, *Ethics in Medicine* (Polity Press 2006) 63 arguing that, morally, the duty to inform the patient adequately is linked with the patient's right of self-determination and his right to choose, legally his 'rights' are largely dependent on the definition of the doctor's duty of care.

[636] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 196; see eg *Chester v Afshar* [2004] UKHL 41(HL), a case decided on causation rather than breach of duty where Lord Steyn remarked obiter that: '… as a result of the surgeon's failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense. Her right of autonomy and dignity can and ought to be vindicated …' and at [92] Lord Walker also commented: '… during the twenty years which have elapsed since *Sidaway* the importance of personal autonomy has been more and more widely recognised'; see also S Devaney, 'Commentary – Autonomy Rules Ok' [2005] Med L Rev 102.

[637] The patient of course has to prove not only the breach of duty by the doctor but also that had the duty been fulfilled he would not have chosen to proceed with the treatment.

in the ongoing debate over the standard of the duty to disclose the law should and does in fact apply.[638]

3.4.1 The standard of disclosure

Commentators have argued that only a subjective patient standard of disclosure would be protective of patient autonomy as only such a standard would provide the information the particular patient requires.[639] Although the subjective patient standard has been supported in some common law jurisdictions[640] the argument against the application of this standard is that it may place too burdensome a legal duty on the doctor and that it would be unworkable in practice.[641] In any case, English law does not recognise a subjective disclosure standard. Rather there is academic debate whether the significance or materiality of the treatment risks which need to be disclosed are to be judged by a standard more favourable to the doctor, a modification of the *Bolam*[642] standard or according to the reasonable patient standard.[643]

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[638] J Jackson, *Ethics in Medicine* (Polity Press 2006) 61.

[639] R Heywood, 'Subjectivity in Risk Disclosure: Considering the Position of the Particular Patient' (2009) 25 PN 3; E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006); M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169.

[640] The US states of Oregon, see *Arena v Gingrich* 733 P 2d 75 (1987) and *Macy v Blatchford* 8 P 3d 204 (2000), West Virginia, see *Cross v Trapp* 294 S E 2d 446 (1982) and of Oklahoma, see *Scott v Bradford* 606 P 2d 554 Okl (1979) 559 (Justice Dooley): 'The Canterbury view certainly severely limits the protection granted an injured patient. To the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient's right of self-determination is irrevocably lost. This basic right to know and decide is the reason for the full-disclosure rule. Accordingly, we decline to jeopardize this right by the imposition of the "reasonable man" standard'.

[641] S McLean, *Autonomy, Consent and the Law* (1st edn, Routledge-Cavendish 2009) 93 argues that it may be intelligible that 'courts cannot listen to each individual's claims about what his or her own particular preferences would have been'.

[642] *Bolam v Friern Hospital Management Committee* [1957] WLR 582, 586 (McNair J): 'A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art… Putting it the other way round, a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view.'

[643] See eg M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103; M Brazier and J Miola, 'Bye-bye *Bolam*: a Medical Litigation Revolution?' (2000) 8 Med L Rev 85; K Mason and D Brodie, '*Bolam*, *Bolam* – Wherefore Art Thou *Bolam*?' (2005) 9 Edin LR 298; J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76.

This debate has been ongoing since the landmark House of Lords case of *Sidaway*[644] where the patient's claim, that the failure to inform her of a small risk of injury of less than 2% to her spinal column during spinal surgery was a breach of the surgeon's duty of care, was rejected unanimously by the Law Lords. However, their Lordships reached this decision by different routes with all, except Lord Scarman, favouring to a greater or lesser degree the *Bolam* standard as the applicable standard.

While Lord Diplock was the staunchest advocate for the application of the strict *Bolam* test, in complete contrast, Lord Scarman in his dissenting speech rejected the *Bolam* test for the question of disclosure of risks, placing his argument around the patient's rights. Approving the reasoning adopted in the US case of *Canterbury v Spence*[645] and the Canadian Supreme Court case of *Reibl v Hughes*,[646] his Lordship opted for the reasonable patient test as the test for risk disclosure: 'The test for materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk.'[647] Lord Templeman applied a different reasoning from the other judges, as he phrased the doctor's duties in contractual terms rather than in terms of duty of care. However, implied in his judgment is not a rejection but a modification of the prudent doctor standard of disclosure. Likewise, Lord Bridge, with whom Lord Keith agreed, recognised that the *Bolam* test should not be applied without qualification. Applying the *Bolam* test did not mean 'to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty' and it was open to the courts to condemn non-disclosure 'where the disclosure of a particular risk

[644] *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871.
[645] *Canterbury v Spence* 464 F 2d 772 (DC Cir 1972).
[646] *Reibl v Hughes* 1980 CanLII 23 (SCC), [1980] 2 S C R 880.
[647] *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, 890.

was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it.'[648]

As the only case turning on the question of the standard of disclosure heard in the House of Lords[649] it is of course regrettable that no clear conclusion can be drawn from the judgment.[650] The issue of the applicable standard arose again in *Pearce*[651] in the Court of Appeal following in the aftermath of *Bolitho*,[652] a House of Lords case which applied the modified *Bolam* test to medical diagnosis and treatment but excluded information disclosure.[653] The case concerned a patient who was pregnant with her sixth child and had already gone two weeks past her delivery date. The consultant advised her to have a normal birth without medical intervention. He did not warn her of the risk of non-intervention of a small (0.1 to 0.2 %) increased risk of still birth, which eventuated. Her claim for failure to disclose this risk was rejected. In the words of Lord Woolf MR:

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[648] *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] A.C. 871, 900.

[649] As Heywood points out, 'technically speaking *Sidaway* has never been formally overruled and remains the definitive House of Lords' authority on the question of breach', see R Heywood, 'Subjectivity in Risk Disclosure: Considering the Position of the Particular Patient' (2009) 25 PN 3.

[650] Kennedy argues that disclosure as described by Lord Bridge comes close to the recognition of the prudent patient test. This was because the question of 'what is a substantial risk of grave adverse consequences' cannot mean to be answered by the medical profession since this would be to re-establish undiluted *Bolam* which Lord Bridge opposed. It was a question for the court to answer and was therefore tantamount to accepting the prudent patient test subject only to the greater emphasis placed on the medical evidence as to the professional standard, see I Kennedy, *Treat Me Right* (OUP 1988) 200–201; cf Brazier and Jones argue that Lord Bridge adopted a qualified *Bolam* standard since by leaving the courts to judge the materiality of the risk and not the doctor the issue whether non-disclosure in a particular case should be condemned as a breach of the doctor's duty of care is an issue decided primarily on the basis of expert evidence, see M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 182 and M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 110–11.

[651] *Pearce v United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA).

[652] *Bolitho v City and Hackney HA* [1998] AC 232 (HL) 243 where in a single judgment for the House of Lords, Lord Browne-Wilkinson held that medical expert evidence would have to have a logical basis, and a doctor cannot escape liability simply because there is a body of professional opinion which sanctions his conduct.

[653] *Bolitho v City and Hackney HA* [1998] AC 232 (HL) 243 (Lord Woolf); cf M Brazier and J Miola, 'Bye-bye *Bolam*: a Medical Litigation Revolution?' (2000) 8 Med L Rev 85, 108 arguing that the question of risk disclosure was specifically excluded by Lord Browne-Wilkinson because he may have 'flagged up the fact that questions of information disclosure were simply not relevant on the facts of *Bolitho* or, more probably, [that] Lord Browne-Wilkinson considered that restraining *Bolam* in the context of information disclosure had already been achieved.'

> In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law … that if there is a significant risk which would affect the judgment of the reasonable patient, then in the normal course it is the responsibility of the doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.[654]

The judgment would appear to suggest that if a reasonable patient would consider a risk significant then the doctor ought to inform him or her of this risk. However, citing *Bolitho* and Lord Bridge's twist on *Bolam* in *Sidaway*, Lord Woolf relied on the medical experts called by the defendant to determine that the small risk in this case was not significant. Both these judgments recognised that medical experts are subject to judicial scrutiny, albeit only *in rare cases*; the disclosure of risks is therefore decided *primarily* by the medical experts.

This leaves the correct position in English law after *Pearce* still open to debate. Brazier and Miola, for example, argue that *Pearce* introduced the reasonable patient test into English law because of their emphasis on the *reasonable patient* in Lord Woolf's judgment.[655] In contrast Maclean places the emphasis instead on the word *significant*.[656] Doing so preserves the professional standard, which is what Lord Woolf did 'by relying on the experts for the determination of the significance of the risk'.[657] As Maclean has stated elsewhere: 'the standard [then] becomes: the doctor

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[654] *Pearce v United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA) 125.
[655] M Brazier and J Miola, 'Bye-bye *Bolam*: a Medical Litigation Revolution?' (2000) 8 Med L Rev 85, 108 emphasising the court's concern with the reasonableness of the patient's assessment of the risk. This view would also be supported by the decision of Sedley LJ in *Wyatt v Curtis* [2003] EWCA Civ 1779 (CA) although Sedley LJ's interpretation of Lord Woolf's refinement of Lord Bridge's test in *Sidaway* has been criticised, see A Maclean, 'The Doctrine of Informed Consent: Does It Exist and Has It Crossed the Atlantic?' (2004) 24 LS 386, 409.
[656] A Maclean, 'The Doctrine of Informed Consent: Does It Exist and Has It Crossed the Atlantic?' (2004) 24 LS 386, 409.
[657] ibid.

must disclose those risks that the reasonable doctor believes the reasonable patient ought to find significant to a decision'.[658]

The correct position in English law is most likely that proposed by Jackson[659] and Jones,[660] namely that *Pearce* has conflated the reasonable doctor and the reasonable patient test so that 'English law applies a test somewhere between the "reasonable doctor" and the "prudent patient" test': no reasonable doctor would fail to disclose a risk regarded as significant by a reasonable patient.[661] This view can also be considered confirmed by the dicta in the House of Lords case of *Chester v Afshar*,[662] appealed on the issue of causation. The content of the doctor's duty was described by Lord Bingham in terms of the surgeon having a duty to warn of a 'small but unavoidable risk';[663] Lord Hope referred to the surgeon as owing a duty to the patient to inform her of risks inherent in the surgery, including the risk of paralysis;[664] Lord Walker stated that 'the surgeon's duty to advise and warn his patient is closely connected with the need for the patient's consent'.[665] Only Lord Hoffman and Lord Steyn appeared to move towards a patient-centred standard of disclosure. Lord Hoffman recognised that failing to warn the patient of risks was 'an affront to her personality'[666] and Lord Steyn's judgment emphasised patient rights,[667] respect for patient autonomy[668] and the end to medical paternalism.[669] However, Lord Steyn expressly approved Lord Woolf's judgment in *Pearce*[670] and its expression of the reasonable patient test in terms of the doctor's duty, although

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[658] A Maclean, 'Beyond *Bolam* and *Bolitho'* (2002) 5 Med LI 205, 214.
[659] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 279.
[660] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 118.
[661] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 279.
[662] *Chester v Afshar* [2004] UKHL 41(HL).
[663] ibid [5].
[664] ibid [55].
[665] ibid [93].
[666] ibid [33].
[667] ibid [16]–[17] where his Lordship opined that 'a patient had a prima facie right to be informed by a surgeon of a small but well established risk of serious injury'.
[668] ibid [18].
[669] ibid [16].
[670] ibid [15].

his Lordship did not clarify who was the arbiter to decide on the *significance* of the risk or the *seriousness* of the risk. The majority support in *Chester* is therefore unlikely for the reasonable patient standard.[671] In any case there is a fundamental problem with the reasonable patient standard: The problem lies in ascertaining the nature and reactions of the mythical reasonable patient.[672] After all, there is no standard patient but only a particular patient.[673]

Of course, the information to be disclosed concerns not only the benefits and risks of a treatment but also alternative treatment options and their attendant benefits and risks. This question has, however, only occasionally been considered by English courts and only little academic commentary has surfaced pertaining to this question.[674] However, 'knowledge of the alternatives may be as significant as knowledge of risks, since a patient may need information about alternative treatments, including the option of non-treatment, so as to compare the risks and benefits of those options with those of the recommended treatment'.[675] The chapter now turns to the requirements for the disclosure of alternative treatment options and in particular the requirements warranting the disclosure of CAM options.

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[671] See eg E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 279 and A Maclean, 'Magic, Myths, and Fairy Tales: Consent and the Relationship between Law and Ethics', in M Freeman (ed), *Law and Bioethics: Current Legal Issues Volume 11* (1st edn, OUP 2008) 120 cf arguments to the contrary are voiced in D Meyers, '*Chester v. Afshar*: Sayonara, Sub Silentio, *Sidaway*?' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 264 and 269; S McLean, *Autonomy, Consent and the Law* (1st edn, Routledge-Cavendish 2009) 82; R Heywood, 'Subjectivity in Risk Disclosure: Considering the Position of the Particular Patient' (2009) 25 PN 3, 3.

[672] M Brazier, 'Patient Autonomy and Consent to Treatment: the Role of the Law?' (1987) 7 LS 169, 189.

[673] ibid.

[674] But see eg J Manning, 'Informed Consent to Medical Treatment: the Common Law and New Zealand's Code of Patient's Rights' (2004) 12 Med L Rev 181, 94; P Skegg, 'English Medical Law and "Informed Consent": an Antipodean Assessment and Alternative' (1999) 7 Med L Rev 7 135, 148; A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (1st edn, CUP 2009) 203.

[675] J Manning, 'Informed Consent to Medical Treatment: the Common Law and New Zealand's Code of Patients' Rights' (2004) 12 Med L Rev 181, 194.

3.4.2 The legal duty to disclose alternatives

A search of English case law has uncovered a few cases where the disclosure of alternatives was considered[676] although it has only been the ratio in one case.[677] Skegg argues that the reason for this negligible emphasis placed on the disclosure of alternatives by English case law and academic discussion is the greater emphasis placed on consent and informed consent, rather than on choice.[678] The reason may also be the earlier strict application of the prudent doctor test to the disclosure duty. As Maclean points out: 'what this means is that, if the treatment is not something that the professional would recommend, and it is reasonable under the *Bolam* test to take this stance, then there may be no duty to disclose the treatment even if another doctor would have recommended it'.[679] Recommendation of a treatment is of course not the same as simply disclosing the existence of the treatment to the patient.

Interestingly, in *Sidaway* it was Lord Scarman (dissenting) who first spoke of the duty to disclose alternatives.[680] Referring to the prudent patient test as enunciated in *Canterbury v Spence*,[681] his Lordship commented:

> I think the *Canterbury* propositions reflect a legal truth which too much judicial reliance on medical judgment tends to obscure. In a medical negligence case where the issue is as to the advice and information given to

[676] See eg *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871; *Pearce v United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA); *Chester v Afshar* [2000] WL 33201379 (QB); *Chester v Afshar* [2002] EWCA Civ 724 (CA).
[677] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) which did not, however, consider the disclosure of alternative *treatment* options but of alternative *diagnostic* methods; but see also *Sem v Mid Yorkshire Hospitals NHS Trust* [2005] EWHC 3469 (QB) where the failure to disclose the treatment alternatives was not disputed by the defendant.
[678] P Skegg, 'English Medical Law and "Informed Consent": an Antipodean Assessment and Alternative' (1999) 7 Med L Rev 7 135, 148.
[679] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (1st edn, CUP 2009) 203.
[680] See also Lord Scarman, 'Consent, Communication and Responsibility' (1996) 79 J R Soc Med 697, 698 where his Lordship spoke of this duty also extrajudicially.
[681] *Canterbury v Spence* 464 F 2d 772 (DC Cir 1972) 787.

> the patient as to the treatment proposed, *the available options* (my italics), and the risk, the court is concerned primarily with a patient's right.[682]

Lord Diplock, who favoured the unmodified *Bolam* test in *Sidaway*, mentioned alternative treatment only in the context of the doctor acting for the benefit of the patient rather than the patient having a choice:

> Advances in the ability to heal resulting from the volume of research, clinical as well as technological … will present doctors with alternative treatments to adopt and a choice to select that treatment (it may be one of several) that is in their judgment likely at the time to prove most efficacious or ameliorating to the health of each particular patient committed to their care.[683]

The case of *Gold v Haringey HA*[684] decided shortly after *Sidaway* concerned a claimant who brought an action for damages when she became pregnant after a sterilisation operation. She alleged that she should have been informed of the risk of failure and also of the alternative to her sterilisation, namely that her husband could have a vasectomy, which was a less invasive procedure and had a greater chance of success. At first instance, Schiemann J agreed with the claimant and distinguished *Sidaway*, holding that the *Bolam* standard only applied to diagnosis and treatment but not to non-therapeutic contraceptive advice. The consultant should have discussed the possibility of a vasectomy and the failure rates of both sterilisation and vasectomy with Mrs Gold. On appeal the judgment was reversed. Lloyd LJ only referred to the speech of Lord Diplock in *Sidaway* as speaking for the House. *Bolam* applied and 'there was a body of responsible medical opinion which would not have given any warning as to the failure of female sterilisation, and the possible alternatives'.[685] The distinction between therapeutic and non-therapeutic advice was

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[682] *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, 888.
[683] ibid 892.
[684] *Gold v Haringey HA* [1987] 2 All ER 888 (CA).
[685] ibid 895 (Lloyd LJ).

'wholly unwarranted and artificial'.[686] The *Bolam* standard applied to all of the doctor's duties.[687]

In *Smith v Salford Health Authority*,[688] a window cleaner was informed of the risks to his health if he did not have corrective cervical surgery on his neck. He underwent the surgery and as result of the surgery became tetraplegic. The surgeon was found negligent in the advice he gave to the plaintiff pre-operatively. There was failure properly to inform the plaintiff of the nature of the surgery, including the benefits of both surgical and non-surgical management. However, the negligent advice was not held to have any causal link with Mr Smith's injuries so he did not succeed in this respect. All the same, Mr Smith was fortunate in succeeding in his claim for negligent performance of the surgery because of the surgeon's use of an incorrect surgical instrument to perform the operation. What is remarkable about the judgment is that Potter J's judgment made no reference to *Sidaway* or *Bolam* and turned solely on its facts.

The subsequent cases of *Pearce*[689] and *Chester*[690] both considered the disclosure of alternative treatments. In *Pearce* the issue was of course not whether Mrs Pearce had been informed of the different treatment options open to her, namely natural childbirth, induced labour and caesarean section – she had begged the consultant to be induced or have a caesarean section – the issue was whether she should have been advised of an increased risk of still birth with natural childbirth.[691] Nevertheless it is

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[686] ibid 896 (Brown LJ).
[687] Reliance on Lord Diplock's approach, ie the unmodified *Bolam* standard, thus led to a rejection of a duty to inform of any alternative treatment without recognising it as a legitimate argument, see I Kennedy, *Treat Me Right* (OUP 1988) 211 .
[688] *Smith v Salford Health Authority* [1994] 5 Med LR 321.
[689] *Pearce United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA).
[690] *Chester v Afshar* [2000] WL 33201379 (QB).
[691] Heywood and others correctly point out that it is dubious practice from a legal perspective that the defendant had explained the risks of the options which he did not recommend but did not explain the risks of the option he preferred, see R Heywood and others, 'Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections' (2010) 18 Med L Rev 152, 178.

clear from Lord Woolf's judgment with its more patient-centred disclosure standard that the disclosure of risks is relevant in a patient's treatment choice.[692]

Chester[693] concerned a working journalist who had suffered from back pain for some years. An MRI scan showed a degeneration of her spinal discs leading to her referral to Mr Afshar, a consultant neurosurgeon. The referring doctor advised Mr Afshar that Mrs Chester was averse to surgery. The latter, however, recommended surgery and performed the operation three days later. The surgery resulted in severe nerve damage and partial paralysis. One of the main aspects of Mrs Chester's case concerned the allegation that the defendant 'failed to advise … her as to the real risks attached to the surgical procedure, thereby depriving her of an opportunity to reflect, consider and/or seek alternative medical or other opinion in respect of options which might be open to her'.[694] One of the experts in the case, for example, suggested that physiotherapy would have been his preferred treatment, at least for the time being, before considering surgery of the same or different kind which the claimant underwent. At first instance Taylor J stated:

> If the Claimant had gone to another consultant, because of her aversion to surgery and her anxiety about the risk of being crippled, it seems to me more probable than not that such a consultant would have tried to meet her concerns … by suggesting some alternative course, if only some different form of surgery … It is unlikely that two or more neurosurgeons would have been unanimous in their advice to the Claimant, and that between them they could have presented her with a number of different options, both surgical and conservative.[695]

The main finding of the trial judge was that Mr Afshar had failed to disclose the small risk of the surgery, that the risk had eventuated and a proper warning of the risk would have dissuaded Mrs Chester from undergoing the surgery when she did.

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[692] *Pearce United Bristol Healthcare NHS Trusts* (1998) 48 BMLR 118 (CA).
[693] *Chester v Afshar* [2000] WL 33201379 (QB).
[694] ibid [43].
[695] ibid [69].

Therefore, sufficient causation had been established between the breach of duty and her injury. The appeal by the defendant surgeon on the issue of causation was dismissed by both the Court of Appeal[696] and the House of Lords.[697] Arguably, however, although this is now a moot point, Mrs Chester was more concerned with the disclosure of other treatment options than with the disclosure of the small but significant risk of the surgery: 'given her pre-existing aversion to surgery …, the very least that she would have done, would have been (as she says) to seek a second, or even third, opinion'.[698] It was the lack of disclosure of risk that directly led to her not obtaining information about alternatives. She might have accepted the same risks at some time in the future, but she had been deprived of the opportunity to make a fully informed choice. As Jackson concludes:

> In a sense, then, it could be argued that the majority [of the House of Lords] found for the claimant *not* because she had proved that the lack of proper information caused her to be exposed to a risk to which she would not have been exposed if she had been properly informed, but rather because she had been deprived of the right to weigh up the risks in order to make an informed choice.[699]

Weighing up of risks always suggests at least two alternatives, even if one of these alternatives is simply 'conservative treatment'.[700] For the patient, information about alternatives will often be as important as information about the proposed procedure.

The only two English cases where the duty to disclose alternatives was directly on point are *Sem*[701] and *Birch.*[702] In the former case, liability was admitted, so that the

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[696] *Chester v Afshar* [2002] EWCA Civ 724 (CA).
[697] *Chester v Afshar* [2004] UKHL 41(HL).
[698] *Chester v Afshar* [2000] WL 33201379 (QB) [64] (Taylor J).
[699] E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn, OUP 2009), 203.
[700] Suggested by one of the expert witnesses in *Chester v Afshar* [2000] WL 33201379 (QB) [69] (Taylor J).
[701] *Sem v Mid Yorkshire Hospitals NHS Trust* [2005] EWHC 3469 (QB).
[702] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB).

case primarily turned on the issue of causation, whereas the latter case concerned the duty to disclose alternative diagnostic methods rather than alternative treatments.

Sem, a case decided after *Chester*, concerned Mrs M, who presented with various symptoms including uterine prolapse. She underwent a surgical procedure which included a vaginal hysterectomy. The primary complaint by Mrs M was not directed at the performance of the operation by the consultant surgeon but to the pre-operative advice which she had not received, namely she had not been advised about other treatments which might have been available. The expert witnesses were agreed that Mrs M should have been informed of the options of doing nothing apart from physiotherapy, the use of medical devices, a surgical alternative to vaginal hysterectomy and three different surgical options. The defendant Trust accepted that failure by the consultant to give any such advice was negligent. Mrs M lost her claim on the issue of causation.[703] Therefore, although the doctor breached his duty to disclose alternatives, the patient did not succeed.

In *Birch*, the patient, Mrs Birch, suffered a stroke caused by a cerebral catheter angiogram. She claimed that the decision to use the angiogram was negligent, and that the investigation of her condition should have been instead by MRI, a non-invasive imaging technique without any major risks. In addition, she alleged that she should have been informed of the availability of both imaging techniques and their comparative risks and benefits.[704] Mrs Birch's condition, painful third nerve palsy, was said to have three possible causes:[705] cause A which might resolve itself spontaneously and was the most likely cause, and causes B and C which were potentially life threatening but C more so than B. B could only be detected by MRI

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[703] Although Mrs M's evidence was that if she had been offered 'a menu of treatments' she would have chosen the least invasive treatment, her evidence was not believed because her psychiatric condition meant that she would not have been satisfied with any treatment other than surgery: 'Individuals with the tendencies towards illness behaviour exhibited by Mrs M tend to seek out more dramatic interventions [rather] than conservative ones.' *Sem v Mid Yorkshire Hospitals NHS Trust* [2005] EWHC 3469 (QB) [55] (Langan J).

[704] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [81].

[705] Cause A: a benign ischemic lesion, cause B: cavernous sinus pathology which was unlikely but possible; cause C: aortic aneurysm which was the most life threatening but also most unlikely as Mrs Birch was a diabetic.

but not with a cerebral catheter angiogram; C could be detected by MRI with 90–95% certainty but with 100% certainty with the angiogram. The angiogram carried a 1% risk of stroke whereas the MRI had no serious risks. Cranston J found the use of the angiogram to rule out an aneurysm was not negligent because there was a responsible body of neurosurgeons who would have taken the same decision, and this decision was capable of withstanding logical analysis.

The case therefore turned on the disclosure issue. Mrs Birch had been informed of the 1% risk of stroke with the angiogram procedure but she was not informed of the comparative risks associated with both procedures. Stating that English law was mainly concerned with the disclosure of 'objectively significant risks',[706] Cranston J held that, although no authority had been cited to this effect, there will be circumstances where a patient has to be informed of comparative risks:

> consistently with Lord Woolf MR's statement of the law in *Pearce v United Bristol Healthcare NHS Trust* the duty to inform a patient of the significant risks will not be discharged unless she is made aware that fewer, or no risks, are associated with another procedure. In other words, unless the patient is informed of the comparative risks of different procedures she will not be in a position to give her fully informed consent to one procedure rather than another.[707]

The judge came to the conclusion that the defendant hospital Trust was liable as 'no reasonable, prudent medical practitioner would have failed to discuss the respective modalities and risks with [Mrs Birch] along the lines outlined. In their absence she was denied the opportunity to make an informed choice.'[708] In case this test was the incorrect one to apply, the judge then sought refuge in *Bolitho*: 'Even, if I am wrong on this, the failure to discuss with Mrs Birch these matters could not be described in

[706] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [74].
[707] ibid [74].
[708] ibid [79].

law as reasonable, responsible or logical'[709] and then concluded: 'on either approach, therefore, the failure to provide her with this information was in breach of duty'.[710] As Jackson argues, the test employed by Cranston J was that of the *reasonable* doctor while following in the footsteps of Lord Woolf's modified prudent doctor test in *Pearce* with its more patient-centred outlook.[711]

The judge limited his ruling to the 'unusual circumstances' of the case, but he did not explain what these circumstances were. Heywood suggests that the unusual circumstances the judge referred to might be that there were two options available of which one was slightly more effective than the other at ruling out a potentially serious condition and that both could have reached a similar diagnosis'.[712] This leads Heywood to conclude that

> where alternative medical (diagnostic) procedures differ substantially in what they are aiming to achieve and the frequency of their success … the alternative medical procedure may simply not be a feasible option and thus it would be inappropriate for the law to hold medical practitioners liable for failure to disclose it.[713]

This argument is unlikely to stand: in *Birch* itself the two imaging techniques were not broadly similar in what they aimed to achieve: the angiogram was unable to exclude condition B[714] and the MRI was not able to exclude condition C[715] with 100% certainly. They were very different diagnostic options with different aims. The unusual circumstances of the case to which Cranston J referred were more likely that Mrs Birch, although referred to the Queen Square centre by one of its consultant *neurologists*,[716] unfortunately had been admitted to the *neurosurgical* department

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[709] ibid [79].
[710] ibid [79].
[711] E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn, OUP 2009) 187.
[712] R Heywood, 'Medical Disclosure of Alternative Treatments' (2009) 68 CLJ 30, 31.
[713] ibid.
[714] Cavernous sinus pathology.
[715] Aortic aneurysm.
[716] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [78].

rather than the neurology department as there were no neurology beds available at that point in time,[717] and neurosurgeons were more likely to consider a cerebral catheter angiogram rather than MRI as their first line diagnostic method in a case presenting as Mrs Birch did.[718]

While the similarity of the diagnostic procedures may therefore not be decisive, the case can be read subject to the standard of disclosure applied in *Pearce* as requiring the disclosure of less risky, feasible and available alternatives. Furthermore, the case is unlikely to be read as restricted to the disclosure of different diagnostic techniques but Cranston J's decision may also have implications regarding the disclosure of less risky, feasible and available alternative *treatment* options.[719] However, the judge was concerned by the uncertainty in the law and was unable to state in general terms when the duty to inform about comparative risks arises.[720] Because of this uncertainty and the paucity of English decisions in this area it is necessary to look to other common law jurisdictions, particularly Canada and the United States with their larger number of disclosure cases, including cases concerning non-conventional treatments.

3.4.3 A legal duty to disclose complementary alternative therapies?

Despite the decision in *Birch* suggesting a legal duty to disclose less risky, feasible and available alternatives, whether doctors could be under a legal duty to disclose CAM options is difficult to establish not only because the common law develops on

[717] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [7].
[718] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [18, 64] referring to an ascertainment bias in the neurosurgical unit.
[719] R Heywood, 'Medical Disclosure of Alternative Treatments' (2009) 68 CLJ 30, 31 where the author argues that 'Birch opens up new avenues for patients should something untoward happen as a result of a decision to proceed with a more invasive and riskier procedure where a similar conservative treatment is a realistic option'; see also A Maclean, 'From *Sidaway* to *Pearce* and beyond: Is the Legal Regulation of Consent Any Better Following a Quarter of a Century of Judicial Scrutiny? (2012) 20 Med L Rev 108, 123.
[720] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [77]; A Maclean, 'From *Sidaway* to *Pearce* and beyond: Is the legal regulation of consent any better following a quarter of a century of judicial scrutiny?' (2012) Med L Rev 108, 122.

a case-by-case basis.[721] After all, can there be a legal duty of disclosing what is seen by many as 'fringe medicine' and not 'mainstream'? To hold doctors liable to disclose all possible treatments, both orthodox and CAM, might subject them to an insurmountable burden and be impossible within the time constraints of the consultation. In any case, the disclosure standard adopted in *Birch* following *Pearce* and *Sidaway* does not suggest the disclosure of options which the *subjective* patient may wish to have to enable her to make a choice. It suggests the disclosure of options which the prudent doctor knows the reasonable patient would wish to have and the determination of this 'abstract hypothetical reasonable patient' is arrived at by the court.[722]

The legal position in Canada and the US

There are some Canadian and US cases on the issue of disclosure of non-orthodox alternative treatments. With its more expansive view of what information the reasonable patient would want in order to make her treatment decision,[723] there is Canadian authority for the duty to inform patients of less dangerous,[724] more conservative,[725] even less effective treatments[726] which may not be the preferred

[721] It also needs to be remembered that many patients, particularly those affected by intractable long-term chronic conditions, may raise the possibility of CAM with their GPs of their own accord, so that the duty regarding the disclosure of the treatment itself is likely to be a moot point.
[722] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 281 where the author takes the argument a step further by assimilating the test with that of the reasonable doctor since doctors, due to small numbers of cases in this area, will seek guidance not from past legal decisions but from other doctors as to what patients would want to know.
[723] The common law jurisdictions of Canada apply a modified objective test of disclosure which is concerned with what the reasonable patient in that particular patient's situation would have wanted to know see, eg *Reibl v Hughes* 1980 CanLII 23 (SCC), [1980] 2 S C R 880.
[724] *Haughian v Paine* (1987) 37 DLR (4th) 624 (Sask CA) concerning non-disclosure of non-treatment or conservative treatment such as supervised rest, muscle relaxants, physiotherapy and pain-relieving medication; *Ferguson v Hamilton Civic Hospitals* 1983 Carswell Ont 705, 40 O R (2d) 577, aff'd (1980) 50 O R (2d) 754 concerning the failure to inform of alternatives to an angiogram, such as no treatment or treatment with heparin and aspirin, although it was recognised that the risks of the alternatives were potentially greater in the long run.
[725] *Haughian v Paine* (1987) 37 DLR (4th) 624 (Sask CA).
[726] *Ferguson v Hamilton Civic Hospitals* 1983 CarswellOnt 705, 40 O R (2d) 577, aff'd (1980) 50 O R (2d) 754.

treatment of the doctor as long as it is an acceptable and known treatment.[727] There is, however, no direct Canadian authority as to whether the duty also applies to complementary therapy options, although dicta exist in a few Canadian cases concerning such disclosure.

For example, in her judgment in *Seney v Crooks*[728] in the Alberta Court of Appeal, based on the particular facts, Conrad JA was careful to restrict a general principle in favour of disclosure of *any* alternatives and sided with the appellants who argued against overextending this duty:

> The duty to inform of alternative treatments placed an unpredictable and monumental responsibility upon the medical profession and one that is much too onerous. For instance, would it be necessary to inform of every possible alternative available, whether or not generally considered reliable by the profession? Would each professional need to become knowledgeable on and inform patients of, alternative medicine practices such as chiropractic treatment or holistic medicine treatments? If the treatment performed complies with the local standard, why should it be negligent to fail to inform of another?[729]

Since the alternative treatment in this case was not complementary or alternative the judge avoided any discussion of whether non-conventional therapies would ever have to be disclosed.

The case of *Santos v Traff*,[730] a decision of the Queen's Bench in Alberta, sheds slightly more light on this question suggesting that there is no duty to advise of fringe or dangerous alternatives. This case concerned a morbidly obese female patient who underwent a hysterectomy and claimed that she had not been told of the

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[727] *Seney v Crooks* 1998 ABCA 316 concerning non-disclosure of a surgical option for a broken wrist rather than the doctor's preferred non-surgical option of applying a cast only.
[728] *Seney v Crooks* 1998 ABCA 316.
[729] *Seney v Crooks* 1998 ABCA 316 [57].
[730] *Santos v Traff* (1999) ABQB 630.

various surgical alternatives prior to her operation. Although she won her case on the issue of negligent performance of the operation, she did not win on the issue of lack of disclosure of alternative treatment options. The conventional alternatives envisaged by the patient were not considered to be reasonable and the court opined on the disclosure of other, non-conventional alternatives:

> [Conrad JA in *Seney v Crooks*] suggests that the plaintiff be advised of *any* available alternatives. I am satisfied that this characterisation is too wide if taken literally and absent the connection to the reasonable patient. In fact, there is no duty to advise of fringe or dangerous alternatives. Common sense suggests that the failure to advise of alternatives might be applied most successfully against the doctor who uses the fringe alternative, or one not generally accepted by the medical profession as within the standard of care, and fails to inform of the medically mainstream alternative.'[731]

In contrast, in two US cases the doctor's duty to disclose complementary alternative therapies was the main issue. *Schiff v Prados*[732] was decided in California, with its patient-based standard of disclosure,[733] and *Moore v Baker*[734] in Georgia, where the disclosure standard at the time of the decision was the professional standard.[735]

Schiff concerned a child diagnosed with a rare and aggressive form of brain cancer. The defendant oncologist suggested different orthodox treatment options including chemotherapy and radiation but did not disclose any non-conventional treatment options. The parents had read of antineoplastons offered as a cancer cure by a doctor

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[731] *Santos v Traff* (1999) ABQB 630 [49] (Smith J).
[732] *Schiff v Prados* 92 Cal App 4th 692 (2001).
[733] See eg *Cobbs v Grant* 502 P 2d 1, Cal SC (1972).
[734] *Moore v Baker* 989 F 2d 1129 C A 11 (1993).
[735] At the time of the hearing, the state law on informed consent, Georgia O.C. Code Ann. § 31-9-6.1(a)(5)(Supp. 1991),required physicians, before performing surgery, to inform patients of the risks and of alternatives 'generally recognised and accepted by reasonably prudent physicians'; see also A Szczygiel, 'Beyond Informed Consent' (1994) 21 Ohio N U L Rev. 171, 210. Georgia now applies the prudent patient test, see *Ketchup v Howard* 543 S E 2d 371 (2000) 373; see also JS King and BW Moulton, 'Rethinking Informed Consent: The Case for Shared Medical Decision-Making' (2006) 32 Am J L and Med 429, 430 and app A which includes Georgia as a state applying the prudent patient test.

in Texas which was, however, opposed by the defendant doctor as toxic and ineffective.[736] As the orthodox treatment had left residual tumour mass, the father took his daughter to Texas where she started the treatment with antineoplastons and then returned home to California with a further supply to be administered intravenously, although he understood that the treatment was not approved by the FDA and that the American Medical Association was critical of it. The child later died, although the tumour had first regressed, with the apparent cause of her death being aspiration pneumonia brought on by radiation necrosis. The parents sued the defendant for lack of informed consent because he had failed to advise them of the antineoplaston treatment. In his defence the oncologist argued that there are many alternative treatments for cancer, including laetrile, vitamin C, immune-augmentative therapy, coffee enemas and Chinese herbal medicine amongst others and, although a patient is free to explore these potentialities, the standard of care does not require controversial and/or alternative methods which have not been subjected to scientific scrutiny to be discussed as possible options with the patient. The plaintiff parents did not succeed in their claim because the antineoplaston treatment was outlawed as a cancer treatment in California and its legality was being litigated in Texas at the time.

Moore concerned a patient who was suffering from a partial blockage of her carotid artery due to atherosclerosis. The defendant doctor recommended that she undergo a neurosurgical procedure known as a carotid endarterectomy but he did not advise her of any alternative, non-conventional treatment options such as EDTA chelation therapy.[737] Following surgery, the patient suffered permanent brain damage. She sued for failure to inform her of the availability of EDTA chelation therapy, an allegedly safer, equally effective therapy, as an alternative to surgery[738] but did not

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[736] Antineoplastons are peptides distilled from human urine. The treatment is based on the alleged significant differences in peptides between the blood of cancer patients and non-cancer patients.
[737] EDTA chelation therapy is claimed to correct the cholesterol metabolism by removing calcium, copper and zinc from the vessel and decreasing platelet aggregation and plaque formation involved in atherosclerosis.
[738] According to a Cochrane review there is insufficient evidence of efficacy of EDTA therapy, see E Ernst and others, *The Desktop Guide to Complementary and Alternative Medicine: An Evidence-*

succeed with her claim. The court held that she had not shown that reasonably prudent physicians generally recognise and accept EDTA chelation therapy. The defendant surgeon had produced evidence that EDTA chelation therapy was not taught in medical schools, was not FDA-approved for treating blocked arteries and had been criticised as unproven by a number of professional associations. Specifically, the court accepted the defendant's evidence that the American Medical Association had concluded that chelation treatment was not an acceptable treatment for atherosclerosis, that the American Heart Association did not recommend it for the treatment of heart disease because the benefits had not been proven scientifically, and that the American College of Cardiology and the American College of Physicians opposed it except on an experimental basis.[739]

Thus, from the decided cases in these two common law jurisdictions, two lines of arguments emerge for disclosure of non-conventional treatment: the treatment has to be open to the patient (*available, feasible and legal*)[740] and reasonable (*medically reasonable and accepted*),[741] both requirements that support and expand on *Birch* and *Pearce*.

Are CAM options open to the patient in England?

The requirement for CAM options to be open to the patient, in the sense of being feasible and available,[742] in order to make disclosure legally mandatory is consistent with the judgment in *Birch* turning on the duty to disclose available and feasible

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Based Approach (2nd edn, Mosby 2006) 311–13 citing MV Villaruz, A Dans, and F Tan, 'Chelation Therapy for Atherosclerotic Cardiovascular Disease' (2002) The Cochrane Database of Sys Rev, issue 4. Art No. CD002785.

[739] *Moore v Baker* 989 F 2d 1129 C A 11 (1993).

[740] *Seney v Crooks* 1998 ABCA 316; *Schiff v Prados* 92 Cal App 4th 692 (2001).

[741] *Santos v Traff* (1999) ABQB 630; *Moore v Baker* 989 F 2d 1129 C A 11 (1993).

[742] The issue of the legality of CAM is not relevant as there are no legal restrictions on the use of any CAM modality by registered medical practitioners as long as the practitioners have the skill and qualifications to use it, see British Medical Association, *Complementary Medicine: New Approaches to Good Practice* (OUP 1993) 5–8 emphasises that under the Medical Act 1858 medical practitioners are permitted to practise whatever form of treatment, conventional or otherwise, they wish; see also C Zollman and A Vickers, 'ABC of Complementary Medicine' (1999) 319 BMJ 901, 903 arguing that any CAM practice would have to be read subject to the standard of care in accordance with the *Bolam* standard.

diagnostic alternatives. Whether CAM is considered feasible will depend to a considerable extent on whether the doctor is aware of CAM or a CAM modality for the condition the patient presents with. CAM itself is defined as 'health ideas and practices not taught in most medical schools',[743] comprising a multitude of treatments from chiropractic to Reiki, traditional Chinese medicine to Indian Ayurveda, to herbal medicine, homeopathy and prayer for healing.[744] Doctors are of course trained in conventional medicine rather than in alternative therapies. A doctor trained in conventional medicine may not be aware of the vast number of treatments and procedures available under the CAM umbrella.

All the same, according to a study in the primary care sector, almost half of the general practices in England provide access to one of the main CAM therapies,[745] either in the practice itself or through referrals.[746] There are CAM familiarisation courses available in some medical schools in England, for example at the Peninsula Medical School, the University of Southampton and University College London although, according to the BMA, coverage is patchy.[747] There is statutory regulation of some CAM therapies.[748] CAM, including homeopathy, is available within the NHS.[749] There is NICE guidance on some CAM for specific conditions.[750] There are publications of clinical trials involving CAM and articles on CAM in all the major

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[743] DM Eisenberg and others, 'Unconventional Medicine in the United States: Prevalence, Costs and Patterns of Use' (1993) 328 NEJM 246.
[744] DJ Hufford, 'Evaluating Complementary and Alternative Medicine: The Limits of Science and Scientists' (2003) 31 J L Med & Ethics 198, 200.
[745] Osteopathy and chiropractic, acupuncture, herbal medicine and homeopathy.
[746] KJ Thomas and others, 'Trends in Access to Complementary or Alternative Medicines via Primary Care in England: 1995–2001 Results from a Follow-up National Survey' (2003) 20 Family Practice 575, 575.
[747] http://www.bma.org.uk/health_promotion_ethics/complementary_medicine/camwhatpatientsmaybeusing.jsp accessed 30 January 2010.
[748] Osteopaths Act 1983 and Chiropractors Act 1994.
[749] The BMA has voted against the continued availability of homeopathy on the NHS, see http://www.guardian.co.uk/society/2010/jun/29/ban-homeopathy-from-nhs-doctors accessed on 30 June 2010.
[750] eg NICE clinical guidelines on treatment of low back pain and on the treatment of multiple sclerosis, at http://guidance.nice.org.uk/CG88/Guidance/pdf/English and <www.nice.org.uk/nicemedia/pdf/cg008guidance.pdf> accessed on 30 January 2010.

medical journals.[751] There is also guidance for general practitioners by the BMA concerning referral and delegation to CAM practitioners.[752] A report has been published on CAM by the House of Lords Science and Technology Committee[753] and a further one has been published by the House of Commons Science and Technology Committee on homeopathy.[754]

While CAM or some CAM modalities can therefore be regarded as feasible, the availability of CAM is a different matter. Publicly funded CAM is only available to a limited extent in the English NHS.[755] It is more widely available through private healthcare, for which consumers pay considerable sums. The personalisation and 'responsibilisation' agenda of policy-makers, illustrated by personal healthcare budgets for patients with long-term chronic conditions, may lead to more public funding of some CAM modalities and make CAM available to patients who were previously unable to afford it privately.[756] There is therefore no easy answer as to whether a doctor could be under a legal duty to disclose CAM treatment options which are only publicly funded to a limited extent. Maclean argues that privately available treatment options ought to be disclosed unless the healthcare professional can be certain that the patient will be unable to pay for the treatment although it

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[751] See eg DM Eisenberg and others, 'Unconventional Medicine in the United States: Prevalence, Costs and Patterns of Use' (1993) 328 NEJM 246; DM Eisenberg and others, 'Trends in Alternative Medicine Use in the United States, 1990–1997' (1998) 280 JAMA 1569; K Linde and others, 'Are the Clinical Effects of Homeopathy Placebo Effects? A Meta-Analysis of Placebo-Controlled Trials' (1997) 359 Lancet 834; PH Canter and others, 'Cost Effectiveness of Complementary Treatments in the United Kingdom: Systematic Review' (2005) 331 BMJ 880.

[752] See http://www.bma.org.uk/images/refcomtherap0406_tcm41-190153.pdf accessed 30 January 2010.

[753] House of Lords, Science and Technology Committee Sixth Report, *Complementary and Alternative Medicine* (HMSO 2000).

[754] House of Commons, *Report of the Science and Technology Committee*, *Evidence Check 2: Homeopathy* (HMSO 2010).

[755] KJ Thomas and others, 'Use and Expenditure on Complementary Medicine in England: A Population Based Survey' (2001) 9 Complementary Therapies in Medicine 2, 3; see also DM Eisenberg and others, 'Trends in Alternative Medicine Use in the United States, 1990–1997' (1998) 280 JAMA 1569, 1569.

[756] The availability of CAM at the micro-level is in practice, however, restricted at the meso-level by primary care trusts and assessment panels deciding on how personal healthcare budgets are spent and by denominating CAM as low priority treatments, see chapter 4.

may, of course, be difficult to ascertain that the treatment is affordable for the patient.[757]

Is CAM a medically reasonable and accepted treatment in England?

Case law from Canada and the US also points to the requirement for the non-conventional treatment to be a medically reasonable and accepted treatment to make disclosure legally mandatory. According to *Santos*, for a doctor to have to disclose every possible treatment alternative would be against common sense. Only reasonable alternatives or treatments which are not entirely unreasonable have to be disclosed. Lack of recognition and acceptance of CAM by the medical community as in *Moore* and also *Seney* therefore negate the disclosure duty. In a litigated case expert evidence as to accepted medical practice will play a significant role, leaving the decision as to the reasonableness of the treatment options in dispute and their disclosure largely in the hands of the medical profession, subject to the court's scrutiny in accordance with *Pearce* and also *Birch*.

The content of the doctor's duty to disclose, following *Birch*, not only includes the disclosure of the alternatives available but also their comparative benefits and risks. Accordingly, the doctor would need to evaluate the benefits and risks of CAM. However, much of CAM has not undergone rigorous scientific testing, so that information disclosure about CAM may present the doctor with considerable difficulty. Even without insisting on CAM adhering to the gold standard validation for its results (proven to be efficacious by double-blind randomised, placebo-controlled clinical trials) most of the currently available CAM remedies do not have scientifically valid proof of efficacy.[758] The lack of validation of the efficacy of

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[757] A Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (1st edn, CUP 2009) 127.

[758] KM Boozang, 'Western Medicine Opens the Door to Alternative Medicine' (1998) 24 Am J L & Med 185, 204 cf JA Bulen, 'Complementary and Alternative Medicine: Ethical and Legal Aspects of Informed Consent to Treatment' (2003) 24 J Legal Med 331, 354–8 pointing to 4000 randomised controlled trials found in the Cochrane Collaboration, an international attempt to develop evidence-based research about conventional as well as CAM treatments, which show that some CAM treatments offer benefits comparable to those of conventional therapy; see also E Ernst and others,

many of these therapies is therefore a major problem, and might effectively bar them from ever becoming available within the NHS.[759] In addition, there is a misconception about the lack of side-effects of some CAM treatments with generally insufficient information about the safety of CAM.[760]

3.4.4 The causation hurdle

Even if the court finds that there is a duty to disclose which has been breached, the patient needs to overcome a further hurdle. She has to prove that the failure to disclose the information has caused her injury. The requirement for causation means that the patient has to show that, but for the doctor's failure to disclose the available treatment option, she would have adopted a different course of action and would have chosen an alternative treatment that was not disclosed and so avoided the harm.[761] In effect, the patient has to show what she would have done in a hypothetical situation if the doctor had not breached her duty of disclosure subject to the modification of the causation principle in *Chester*.[762]

The Desktop Guide to Complementary and Alternative Medicine: An Evidence-Based Approach (2nd edn, Mosby 2006).

[759] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 73 cf MF Ruggio, 'Complementary and Alternative Medicine: Longstanding Legal Obstacles to Cutting Edge Treatment' (2009) 2 J Health & Life Sci L 137, 152, citing KM Boozang, 'Potential Pitfalls in Providing CAM and Innovative Therapies', Seminar Materials, Annual In-House Counsel Program Meeting, A. Health Lawyers Ass'n (24 June 2007) arguing that a review of randomised controlled trials found in the Cochrane library suggests that conventional medicine is more dangerous than its CAM counterpart. However, as Ruggio points out, at 153, such data need to be kept in perspective: 'CAM modalities tend to treat less threatening conditions and treat them in ways less likely to lead to serious health consequences or death.'

[760] E Ernst, 'Direct Risks Associated with Complementary Medicine' (1996) Complementary Medicine 112, 112 arguing that there is concern about patients' complacency towards potential risks, often believing that alternative treatments are natural and therefore not harmful; KM Boozang, 'Is the Alternative Medicine? Managed Care Apparently Thinks So' (2000) 32 Conn L Rev. 567; E Ernst and others, *The Desktop Guide to Complementary and Alternative Medicine: An Evidence-Based Approach* (2nd edn, Mosby 2006) describing risks of acupuncture , chiropractic and herbal remedies, but the authors also conclude that there are some CAM modalities which are no less effective and have fewer adverse effects than conventional therapies, eg acupuncture for back pain (at 295), osteopathy for low back pain (at 343), St John's Wort for mild to moderate depression (at 463).

[761] *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med LR 285; see also M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 120.

[762] *Chester v Afshar* [2004] UKHL 41(HL) which allows the conclusion that it would be sufficient in a case of non-disclosure for the patient to show that he might have obtained a second or third

The failure to give information about alternative treatments will generally not tend to result in physical injury.[763] English law uses a hybrid objective/subjective test to determine whether or not the claimant would have consented to the treatment he or she actually received if he or she had had the missing information, coupled with a consideration of extraneous factors to substantiate the patient's assertion.[764] As Jones points out, it is the rules of causation as much as the rules on breach of duty which lead to the low success rate of claimants in informed consent cases.[765] The difficulty of proving causation may even form the greater impediment to success.

The English courts may well have attempted to balance patients' informational requirements with policy-based considerations to stem the escalation of costs of medical negligence cases.[766] In the tort of trespass there may also have been an unwillingness to label well intentioned doctors 'batterers'.[767] In the tort of negligence there may have been an unwillingness to accept what, in practice, amounts to strict liability for adverse events on the basis of a failure of information

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opinion if he had had the information of alternatives; see also C Foster, 'It Should Be Therefore It Is' (2004) 154 NLJ 1644, 1645.

[763] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 287.

[764] *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med LR 285, 289; see also E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 287.

[765] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 121–23.

[766] S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 95; M Brazier and E Cave, *Medicine, Patients and the Law* (5th edn, Penguin Books 2011) 239 referring to an estimate of total liability in relation to malpractice cases (including the costs of not yet reported incidents) in 2009/10 of £14.9bn; JK Mason and GT Laurie, *Mason and McCall Smith's Law and Medical Ethics* (8th edn, OUP 2011) 122; see also NHS Litigation Authority, Factsheet 2: Financial Information (2011) stating that the total liability for medical negligence cases on 30 March 2011 had risen to £16.6 bn; see also the extrajudicial comments by Lord Irvine of Lairg, 'The Patient, the Doctor, Their Lawyers and the Judge: Rights and Duties' (1999) Med L Rev 255, 267 querying whether the traditional approach of compensating claimants for medical negligence was necessarily the best one; and by Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) Med L Rev 1, 2 referring to the costs of medical negligence litigation as a disaster area.

[767] H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 134; G Seabourne, 'The Role of the Tort of Battery in Medical Law' (1995) Anglo-American L Rev 265, 273; E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 277.

disclosure.[768] Thus, despite macro-level policies, tort law is not protecting the patient's rights to adequate information about orthodox treatment and even less about CAM treatment. While the law of trespass has almost completely failed to help the uninformed patient, patients have only been successful in a minority of cases in cases of informed consent in the law of negligence.[769] However, despite this legal imbalance between doctor and patient, litigation and the risk of litigation by uninformed patients suing medical practitioners in tort law has not been without effect. They have had destabilising effects and led to changes in healthcare practices. It is to these the chapter now turns.

3.5. Patients' rights to information under GMC guidance

Litigation, albeit infrequent, by inadequately informed patients has clearly had an effect on medical practice and regulation. Litigation in medical tort law does not operate as a mere system of dispute resolution with precedential effects. As Sabel and Simon assert, litigation and adjudication in tort law have polycentric effects; they act as a system of social regulation.[770] Medical informed consent litigation has provided a stimulus to the debate about the nature of the doctor-patient relationship generally.[771] Litigation and subsequent adjudication, although of little benefit to most patients immediately involved, have encroached on the doctor/patient relationship generally and on the regulation of medical practice. Doctors have become more sensitive to the risk of litigation and pay increased attention to the question of obtaining patients' consent and ensuring that they are adequately

[768] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 287; G Robertson, 'Informed Consent to Medical Treatment' [1981] LQR 102, 110.

[769] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 121–23. where the author compares the Canadian data on claimant success in informed consent cases presented by G Robertson, 'Informed Consent Ten Years Later: The Impact of *Reibl v Hughes'* (1991) 70 CBR 423 with those in England. The negative outcomes for claimants in Canada were also reflected by the English cases. In his 1998 survey, of the 30 informed consent cases which had gone to trial only seven were successful, nineteen cases had failed on both breach of duty and causation with a further four failing on causation but succeeding on breach.

[770] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1057.

[771] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 130.

informed.[772] As Jones pointed out over a decade ago, in the UK, leaders of the medical profession have begun to respond to the demands for greater openness and information disclosure with the issuing of detailed guidance by the GMC.[773] Although its guidance is not legally enforceable, doctors look to the GMC for guidance on professional and ethical standards. As Jackson states, '[D]octors wanting to know what they should disclose to [a] patient will usually consult professional guidance, rather than the law reports and so in practice the inadequacies of tort law may have little practical impact upon the provision of information to patients.'[774] However, professional guidance goes beyond the common law regarding the information a doctor has to give to the patient.[775]

The first specific guidance on consent, *Seeking Patients' Consent*[776] published by the GMC in 1998, placed much more onerous duties on the doctor regarding the provision of information than the common law. Before this specific guidance the issue of 'informed consent' had not been spelt out in any great detail by the GMC. Rather, consent had only been dealt with in the form of general bullet points as generic guidance in the GMC's core guidance *Good Medical Practice*.[777] *Seeking Patients' Consent* dealt with detailed issues of informed consent including the disclosure of treatment options and the need to explain for each option the likely benefits and the probabilities of success.[778] However, more importantly, it emphasised the importance of effective communication and open helpful dialogue to strengthen the doctor/patient relationship and to provide a framework within which

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[772] ibid 124.
[773] ibid 130 referring to General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998).
[774] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 286.
[775] J Miola, *Medical Ethics and Medical Law, A Symbiotic Relationship* (OUP 2007) 83; M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 130–33; A Maclean, 'The Doctrine of Informed Consent: Does it Exist and Has It Crossed the Atlantic?' (2004) 24 LS 386, 412; S McLean, *Autonomy, Consent and the Law* (Routledge-Cavendish 2010) 95–96.
[776] General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998).
[777] S Fovargue and J Miola, 'One Step Forward, Two Steps Back? The GMC, the Common Law and "Informed" Consent' (2010) 36 J Med Ethics 494, 494 referring to General Medical Council, *Good Medical Practice* (GMC 1995) [11] and General Medical Council, *Good Medical Practice* (GMC 1998) [12].
[778] General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998) [5].

the doctor can respond effectively to the individual needs of the patient.[779] The doctor must do her best to find out about patients' individual needs and priorities including their 'beliefs, culture, occupation or other factors which may have a bearing on the information they need to reach a decision'.[780] Doctors should not make assumptions about patients' views. They should also provide patients with appropriate information including explanations of any risk to which patients may attach particular significance.[781] In addition and contrary to the common law position, the guidance also spoke of the patient's *right* to make informed decisions as a right protected in law.[782]

As has been demonstrated, the common law does not provide the patient with the *right* to be given sufficient information but restricts the duty of the doctor under the law of negligence to provide information according to a standard which lies somewhere between that of the reasonable doctor and the reasonable patient and further requires proof of causation to establish liability. The 1998 guidance, on the other hand, described a disclosure standard which comes close to that of the subjective patient, imposing a duty on doctors to tailor their disclosure to the patient's priorities.[783] While a subjective test may be impractical as a test to ground legal liability in negligence,[784] increased informed consent litigation since the early 1980s has clearly motivated the GMC to adopt this more stringent test in its guidance, whether or not erroneously believing at the same time that case law backs the patient's *right* to information.[785]

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[779] ibid [3].
[780] ibid [6].
[781] ibid [6].
[782] ibid [2]; see also M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 133.
[783] E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn, OUP 2009) 190.
[784] ibid, arguing that within the increasingly impersonal healthcare system doctors cannot be expected to know enough about the values and experiences of individual patients to realise what factors matter for their decision-making.
[785] M Jones, 'Informed Consent and other Fairy Stories' (1999) 7 Med L Rev 103, 130.

The current guidance on consent, *Consent: Patients and Doctors Making Decisions Together*,[786] published in 2008, is even more detailed regarding the exchange of information between doctor and patient than the previous guidance. It emphasises that the approach to discussion about treatment will vary between patients, with individual patients wanting more or less information than others.[787] It stresses that discussions about treatment must include information about treatment options and their potential benefits, risks and burdens and the likelihood of success.[788] Like the 1998 guidance, the current guidance also adopts a higher disclosure standard than the common law and adopts an approach approximating to the subjective standard of disclosure. Thus, doctors should tailor the exchange of information with the patient according to the patient's needs and wishes, their level of knowledge about, and understanding of, their condition, prognosis and the treatment options, the nature of their condition and the complexity of treatment.[789] Doctors should not make assumptions about the information a patient might want or need and the clinical or other factors a patient might consider significant.[790] The guidance is also more detailed about the discussion of side effects, complications and other risks, stating that the doctor must identify the adverse outcomes that may result from the proposed options including the failure of an intervention to achieve the desired aim.[791] The doctor should do her best to understand the patient's views and preferences about any proposed investigation or treatment, and the adverse outcomes patients are most concerned about.[792]

While the 1998 guidance emphasised the link between the provision of information with patient autonomy and patient rights, seeing them as a prerequisite for patient cooperation with treatment, the 2008 guidance emphasises the need for partnership

[786] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008).
[787] ibid [4].
[788] ibid [9].
[789] ibid [7].
[790] ibid [8].
[791] ibid [29].
[792] ibid [31].

between doctor and patient when making decisions about treatment and care.[793] With its continuing trend towards a disclosure standard which is more respectful of patients' informational requirements than the common law, and read together with the GMC's core guidance *Good Medical Practice*[794] which asks doctors to support patients' self-care[795] and encourages the involvement of the expert patient in treatment decisions,[796] the 2008 guidance may even suggest the disclosure of alternative treatment options to include disclosure of some of the more common CAM modalities.[797] Patients, especially those with long-term chronic conditions, may wish to be informed of CAM options and many will be raising the subject of CAM use with their GP. Many conditions, especially chronic ones, do not respond well to biomedical treatments,[798] and most CAM tends to be used for problems such as chronic illness or chronic pain, for which conventional medicine sometimes has little to offer.[799] As witnessed by the use of CAM and referral for CAM in general practice, the standard of medical practice clearly far exceeds the restrictive legal disclosure duty concerned with the feasibility, availability and general medical acceptance of treatment options. While tort law may provide little comfort for the uninformed patient, its destabilising effects have led to a change in professional guidance regarding information disclosure.

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[793] ibid part 1; J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2008) 17 Med L Rev 76, 106.
[794] General Medical Council, *Good Medical Practice* (GMC 2006).
[795] ibid [4] and [21e].
[796] ibid [21f].
[797] See General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008).
[798] MF Ruggio, 'Complementary and Alternative Medicine: Longstanding Legal Obstacles to Cutting Edge Treatment' (2009) 2 J Health & Life Sci L 137 citing AM Knoll, 'The Reawakening of Complementary and Alternative Medicine at the Turn of the Twenty-First Century: Filling in the Void in Conventional Biomedicine' (2004) 20 J Contemp Health L & Pol'y 329, 358.
[799] J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn, Routledge 2002) 15; MF Ruggio, 'Complementary and Alternative Medicine: Longstanding Legal Obstacles to Cutting Edge Treatment' (2009) 2 J Health & Life Sci L 137 citing H Morreim, 'A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science' (2003) 31 J L Med & Ethics 222, 230; see also DM Eisenberg and others, 'Trends in Alternative Medicine Use in the United States, 1990–1997' (1998) 280 JAMA 1569, 1573 mentioning chronic conditions such as back problems, neck problems, depression, headaches and anxiety as the conditions for which CAM modalities are most used.

3.6. Conclusion

Although information is central to the current policy-makers' policy of treatment choice it has been demonstrated that the doctrine of informed consent under both the torts of trespass and negligence has been of little benefit to safeguard patients' rights to information. If the interest in providing information involved the patient's right to make an informed choice it would be more logical for the failure to disclose to vitiate the patient's consent, turning the treatment into trespass. The courts have preferred to impose liability for lack of information in negligence rather than trespass, making it necessary for the claimant to show physical injury in the form of the risk materialising. The problems of proving a breach of duty to disclose treatments which are not mainstream, based on the standard as expounded in *Sidaway* and *Pearce* and followed in *Birch*, together with the likely requirements of feasibility, availability and medical acceptance of these treatments drawn from the case law of other common law jurisdictions, and of proving causation, are minimising claimants' chance of success.[800] These problems contribute to what was described by Jackson as the 'impotence of tort' in protecting patients' interest in information disclosure.[801]

However, as has been argued, informed consent litigation although mostly unsuccessful has had implications for medical practice. It has led to changed guidance by the GMC regarding information disclosure and has therefore increased attention by doctors to ensuring that their patients are adequately informed. Both *Seeking Patient' Consent*[802]and *Consent: Patients and Doctors Making Decisions Together*[803] have encouraged more detailed disclosure by doctors with a disclosure standard that fulfils the requirements of patient autonomy in its liberal sense. Read

[800] J Manning, 'Informed Consent to Medical Treatment: the Common Law and New Zealand's Code of Patient's Rights' (2004) 12 Med L Rev 181, 207.
[801] E Jackson, 'Informed Consent to Medical Treatment and the Impotence of Tort' in SA McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006).
[802] General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998).
[803] General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008).

together with the GMC's core practice guidance[804] doctors may be under the impression that they are required to inform patients about CAM, particularly patients with long-term chronic conditions where orthodox treatments may be of little benefit.

Thus, tort law litigation and adjudication, rather than destabilising because of the occasional payment of damages to the patient or because of the precedential effect of adjudicated cases, has destabilising effects with much wider implications for the healthcare system, destabilising and changing medical practice[805] and leading to some redress in the power imbalance between patient and doctor. The next chapter discusses the even greater destabilising effects demonstrated by litigation or possible litigation at the meso-level where the patient wishes to assert her treatment choice against the health authority as a quasi- consumer in the healthcare market.

[804] General Medical Council, *Good Medical Practice* (GMC 2006).
[805] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1057.

Chapter 4
Meso-level destabilisation: Judicial review litigation as a driver for change supporting patient choice of low-priority treatments

4.1. Introduction

Despite the claim of comprehensiveness in the NHS Constitution,[806] financial constraints mean that limits are placed on healthcare so that it is affordable. At the meso-level it is the health authorities, at present PCTs and in future Clinical Commissioning Groups (CCGs), that are entrusted to make resource allocation decisions from their fixed yearly budgets.[807] For this purpose some treatments such as CAM are not generally available, either because the PCT has placed them on a list of so-called low-priority treatments[808] or, as in the case of novel cancer drugs, they have not been approved or are pending approval by the National Institute for Health and Clinical Excellence (NICE). However, a patient can make an individual funding request (IFR) to her PCT supported by her GP to obtain such a drug or treatment on the basis of her exceptional circumstances and, if her request is refused, may look to the courts for judicial review of the decision. The role of the court is to oversee the legitimacy, procedural propriety and reasonableness of the decision, rather than assessing the merits of the patient's claim.[809] In reaching its decision the court will review and rule on the appropriateness of the criteria considered by the PCT for judging a case as exceptional.

This chapter discusses the definition of exceptionality and the exceptionality criteria emerging from judicial review case law which are very general and sometimes

[806] NHS Constitution 2012, 1.
[807] National Health Service Act 2006 s 230; see also Health and Social Care Act 2012, s 223I with regard to CCGs.
[808] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA); see also C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 307.
[809] *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374, 410.

ambiguous,[810] leading to uncertainty for patients as well as health authorities. To analyse the principles developed by the courts in this context, the cases have been grouped into judicial review of IFRs concerning the treatment of life-threatening conditions[811] and of IFRs for low-priority, non-life-threatening treatment.[812] Both groups share a series of criteria which are appropriate for judging a case as exceptional. However, factors such as the effectiveness and the cost-effectiveness[813] may be particularly difficult to assess where the IFRs concern low-priority, non-life-threatening CAM treatments.

It is argued that the ambiguity of the criteria for judging a case as exceptional is not only likely to encourage increased litigation by patients who are refused the low-priority treatment of their choice but will also have a destabilising impact on health authorities. Whether or not the individual patient achieves the desired result, a judicial review challenge has implications beyond the particular parties to the case. Although it is a vehicle by which the individual patient can bring pressure on the PCT – PCTs may often negotiate an agreement with the patient rather than incur the costs of litigation and encourage further claims –, judicial review adjudication can lead to a change in the status quo, leading to public engagement, deliberation and negotiation, with effects on other institutions and practices.[814] In view of the macro-policies of choice, personalised healthcare agenda and personal healthcare budgets,

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[810] See generally A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1; J Maybin and R Klein, *Thinking about Rationing* (King's Fund, London 2012) 26.

[811] eg *R v North Derbyshire Health Authority*, ex p Fisher (1997) 8 Med LR 327; *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin); *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin); *R (Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin).

[812] eg *R v North West Lancashire HA, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA); *R (AC) v Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin) and *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247.

[813] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA), 412; see also C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 313 stressing that evidence of effectiveness may often be incomplete, ambiguous or uncertain; A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 28 and n138.

[814] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1055 making this argument in the context of judicial review of the decisions of public authorities in the US.

the destabilising effects of judicial review challenges have the potential to lead to a greater role for CAM within the NHS.

The chapter first discusses the roles of the PCT, NICE clinical guidelines and the court in judicial review litigation, before turning to the case law defining exceptionality and exceptionality criteria.

4.2. Resource allocation decisions

Rationing of healthcare has been a necessity from the inception of the NHS, despite the value of comprehensiveness underlying its foundation and enshrined in the NHS Constitution.[815] Rationing is, however, no longer a purely implicit restriction of healthcare by the medical practitioner, but has, with the introduction of the internal market, become more explicit and visible.

4.2.1 The roles of the PCT and NICE

It is the local health authorities or primary care trusts (PCTs) that have the unenviable task of deciding which treatments are available and which are restricted for a variety of reasons.[816] PCTs have the statutory duty, delegated to them by the Secretary of State, to commission medical services as they consider necessary to meet the healthcare needs of the local population and within allocated resources.[817]

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[815] NHS Constitution 2012, 1; see also chapter 1.

[816] Since 2005 PCTs have been able to transfer their responsibilities to GP practices to commission services enabling 'practice based commissioning' under which GP practices will take on responsibility from their PCTs for commissioning services that meet the health needs of their local population; see Department of Health, *Commissioning a Patient-Led NHS,* http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4116717.pdf, accessed on 6 September 2011; see generally M Brazier and E Cave, *Medicine, Patients and the Law* (5th edn, Penguin Books 2011) 8. In the context of a demand for CAM by the patient, the definition of appropriateness and also availability is then left to the GP and the GP practice. It remains to be seen whether the Health and Social Care Act 2012 may not have a similar effect on decision-making regarding the availability and appropriateness of CAM by CCGs. Unlike PCTs, the CCGs do not make decisions at arm's length from patients and may therefore be exposed to greater external pressure from patients, patient support groups, the media etc.; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 31 commenting on the possible increased pressure on GPs under CCGs.

[817] National Health Service Act 2006 s 1 imposes a duty on the Secretary of State *to promote* a comprehensive health service and s 3 describes these duties in more detail, stating that the Secretary of State must provide '*to such extent as he considers necessary to meet all reasonable*

In doing so, PCTs must not exceed their annual financial allocations.[818] As each PCT makes its own budgetary choices, one of the inevitable consequences is the so-called postcode rationing or lottery, leading to inequitable geographical access to treatment.[819]

NICE was established in order to end unequal access to treatments and to increase consistency in local decision-making. PCTs are under a legal obligation to make available, within three months, health interventions recommended by NICE in a technology appraisal guidance (TAG).[820] Having to cover the costs of these mandatory TAGs from their existing budgets causes inevitable funding implications for PCTs.[821] PCTs will have to divert funds and reduce expenditure on other treatments or be in breach of their legal duties.[822] However, not all guidance issued by NICE is mandatory. In contrast to TAGs, clinical practice guidelines, such as

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requirements' (e) such facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service, [and] (f) such other services as are required for the diagnosis and treatment of illness and under s 7 these duties are executed by the PCTs on behalf of the Secretary of State; cf under the Health and Social Care Act 2012 s 13 these duties are executed by the Clinical Commissioning Groups (CCGs).

[818] National Health Service Act 2006 s 230; see also Health and Social Care Act 2012, s 223I with regard to CCGs.

[819] See eg J Maybin and R Klein, *Thinking about Rationing* (King's Fund, London 2012) 37 where the authors give the example that the rate of bariatric surgery is up to 38 times greater between different PCT populations; see also chapter 1.

[820] Department of Health, 'Further Directions to Primary Care Trusts and NHS Trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Health and Clinical Excellence (NICE) 2010' reinstating the Directions of 2003, which require PCTs to set aside funds from their existing budgets to cover the costs of positive technology appraisals conducted by NICE, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_114087.pdf, accessed on 5 August 2012.

[821] C Newdick, 'Accountability for Rationing – Theory into Practice' (2005) J L Med & Ethics 660, 666 querying whether the funding of the technology appraisal guidance should take priority over everything else; K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007) *31.*

[822] C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 94; C Newdick, 'Accountability for Rationing – Theory into Practice' (2005) J L Med & Ethics 660, 666 referring to the wide variation among PCTs in the uptake of NICE guidance on the treatment of cancer in breach of their statutory duty making them amenable to judicial review.

NICE guidelines concerning the use of CAM in specific conditions, are not mandatory.[823]

The greater visibility of rationing since the 1990s[824] has brought the issue of treatment denial into public consciousness.[825] Maybe partially encouraged by the NHS choice policy, the number of IFRs by patients for treatments which have been restricted in some form by their PCT is considerable.[826] The means to challenge the refusal of an unsuccessful IFR is by judicial review of the decision of the PCT. The role of the courts in reviewing and shaping the decision-making of health authorities will be discussed next before considering the principles for funding on the basis of exceptional circumstances which emerge from the judicial review cases.

4.2.2 Judicial review challenges and the perceived role of the courts

Not only are judicial challenges to resource allocation decisions considered to be difficult for patients to win[827] but the nature of judicial review, which sets limits to challenging the substance of policy decisions, limits the ability of the court to influence the decision-making of the health authority. The courts are not concerned with the substantive merits of the decision but with the propriety and the transparency of public authority decision-making. As Sir Thomas Bingham MR opined in the case of *Child B*:

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[823] NICE has never carried out a health technology appraisal of CAM so that there has never been mandatory positive guidance on the use of CAM in the NHS, see E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350.

[824] K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007) 159 pointing out that there were very few legal challenges to resource allocation decisions before the case of *R v Cambridge Health Authority, ex p B* [1995] 1 WLR 898.

[825] N Daniels and J Sabin, *Setting Limits Fairly* (OUP 2008) 160.

[826] M Richards, 'Improving Access to Medicines for NHS Patients' (Department of Health, 2008) 63 referring to a total of 26,000 applications for funding for England in 2007, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089952.pdf accessed on 30 September 2012.

[827] K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007) *132–33;* C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 93; B Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom' [2003] Journal of Comparative Policy Analysis 149, 151.

> the courts are not, contrary to what is sometimes believed, arbiters as to the merits of cases of this kind. Were we to express opinions as to the likelihood of the effectiveness of medical treatment, or as to the merits of medical judgment, then we should be straying far from the sphere which under our constitution is accorded to us. We have one function only, which is to rule upon the lawfulness of decisions. That is a function to which we should strictly confine ourselves.[828]

Even where a challenge is successful the court will generally not invalidate the decision but refer the matter back to the authority for re-consideration in the light of the court's observations.[829] As long as the defects in the original decision-making process are remedied, the PCT is entitled to come to the same decision.[830]

Orthodox theory refers to four public law grounds, namely the grounds of illegality,[831] unreasonableness,[832] procedural impropriety[833] and proportionality,[834]

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[828] *R v Cambridge Health Authority, ex p B* [1995] 1 WLR 898, 905 *which concerned* the case of a child who had undergone lengthy leukaemia treatment and was expected to have only a few weeks left to live. Judicial review was sought against the health authority's refusal to fund further costly chemotherapy because of its limited chance of success.

[829] C Newdick, 'Accountability for Rationing – Theory into Practice' (2005) J L Med & Ethics 660, 661.

[830] B Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom' [2003] Journal of Comparative Policy Analysis 149, 152.

[831] Illegality generally describes the case where a health service body has express powers conferred upon it by statute and acts outside these powers, exceeding its jurisdiction; cf where the duties of the public body are expressed in inexact terms the assertion of illegality will not succeed, see eg *R v Secretary of State for Social Services, ex p Hincks* [1980] 1 BMLR 93; see discussion in C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 94–95 and C Foster, 'Simple Rationality? The Law of Healthcare Resource Allocation in England' (2007) 33 J Med Ethics 404, 404.

[832] Irrationality or '*Wednesbury* unreasonableness' applies to 'a decision which is so outrageous in its defiance of logic or of accepted moral standards that no sensible person who had applied his mind to the question to be decided could have arrived at it', see *Associated Provincial Picture Houses v Wednesbury Corp* [1948] 1 KB 223. This definition has been increasingly relaxed to include not only decisions defying comprehension but also those based on flawed logic, see C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 97 citing Lord Woolf in *R v North and East Devon Health Authority, ex p Coughlan* [2001] QB 213, 244.

[833] Procedural impropriety has been described as entailing more than a breach of the principles of natural justice, see *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374, 411 (Lord Diplock); however, a failure to develop a transparent framework which treats patients equally, fairly and consistently exposes the health authority to the risk of challenge on the ground of procedural impropriety, see C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 108.

upon which a patient's challenge might succeed against the decision by a health service body to refuse a particular treatment, and have her case remitted for reconsideration. There is a certain fluidity between the relevant heads of judicial review, so it is not always easy to ascertain upon which basis the courts have arrived at their conclusions.

Since judicial review is concerned with the process of administration rather than the merits of a case the courts permit considerable discretion to health service bodies to establish priorities of expenditure in whichever manner they choose,[835] and the discretion permitted tends to be broader still where financial constraints are admitted by the health authority.[836] However, despite their wide discretionary power when deciding on the allocative priorities in their geographical area, any general policies set by health service bodies must admit of exceptional cases. As Auld LJ stated in *A*,

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[834] The principle of proportionality was already contemplated as the fourth ground for judicial review by Lord Diplock in *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374, 410. It 'requires a court to assess the balance struck between competing interests by the decision-maker and the relevant weight accorded to interests and considerations' and to examine the justifications and reasons given by the decision-maker for the decision', K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007) 167. The need for the articulation of the internal logic of a decision and the reasoning behind it replaces the strict *Wednesbury* unreasonableness test with one that approaches that of proportionality, see E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn, OUP 2009) 88 stating that the Human Rights Act 1998 has already led the courts to emphasise the principle of proportionality when assessing health authorities' decisions of treatment refusal, whether or not patients can claim that Convention rights are engaged; see also K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007) 239 suggesting that the *Wednesbury* unreasonableness test is likely to be replaced in future by that of proportionality even outside the human rights context. To date, no cases on resource allocation or on exceptionality review where a breach of the rights under the ECHR was alleged have been decided on this basis. The reason for this may be that many of the Convention rights are limited or qualified in nature, or that the courts consider the Convention Articles to add nothing to domestic law, see generally C Foster, 'Simple Rationality? The Law of Healthcare Resource Allocation in England' (2007) 33 J Med Ethics 404, 405; see also M Brazier and E Cave, *Medicine, Patients and the Law* (5th edn, Penguin 2011) 33; cf in cases where Convention rights are engaged, the court is likely to subject the refusal to fund treatment by a health authority to still greater scrutiny, see eg *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin) but the intensity of the scrutiny of the decisions may amount to no more than a 'super-*Wednesbury*' review which is 'sufficiently intense to ensure that the matter has been given proper attention', see C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 125.

[835] K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007)177.

[836] K Syrett, 'Opening Eyes to the Reality of Scarce Health Care Resources? *R. (on the application of Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health*' (2006) PL 664, 670.

D and G,[837] a case concerning the blanket refusal of gender reassignment surgery by the PCT*:*

> The precise allocation and weighting of priorities is clearly a matter of judgment for each Authority … It makes sense to have a policy for the purpose – indeed, it might well be irrational not to have one – … It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in 'exceptional circumstances'…[838]

At the same time, however, when exercising their discretion health authorities are entitled to make lists of treatments which are of low priority. Thus in *A, D and G*[839] Auld LJ stated the principle:

> It is natural that each Authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention … and it makes sense too that, in settling on such a policy, an Authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure.[840]

Therefore certain marginal but possibly life-saving treatments, such as many of the novel and expensive cancer drugs, may not be funded by some PCTs because they have not been approved by NICE or they are still awaiting approval. Other treatments which are non-life-saving treatments such as CAM, or so-called 'luxury' treatments[841] such as cosmetic surgery or treatments for non-critical illness,[842] may be ranked as low priority by different health authorities.

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[837] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA).
[838] ibid 412.
[839] ibid.
[840] ibid 415.
[841] C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 307 speaking of 'luxury care treatment'.

While PCTs have therefore wide discretionary powers the courts have developed exceptionality criteria in a series of judicial review cases[843] which PCTs need to consider when patients make individual funding requests.[844] In the following, the chapter discusses exceptionality case reviews by the courts of treatment requests refused by PCTs and discusses the sometimes vague and ambiguous exceptionality criteria as defined in the case law potentially causing legal uncertainty for both patients and PCTs.

4.3. Exceptionality case reviews

Subject to the different public law grounds, as long as their policies allow for 'exceptions' or for 'exceptional circumstances' PCTs have considerable discretion in determining how to allocate resources and set priorities.[845] While it is not necessary to define the specific exceptional circumstances it has to be possible to envisage there being exceptions, such as the possibility of there being an overriding clinical need, since 'if it is not possible to envisage such circumstances the policy would in practice be a complete refusal'.[846] Although it may be difficult to determine exceptional circumstances in advance, as Ford argues, 'to leave the circumstances undefined presents a considerable challenge for PCT policy makers and results in

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[842] *R v Sheffield Health Authority, ex p Seale* (1994) 25 BMLR 1, 3 (Auld LJ).

[843] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) was the first case decided on the basis of exceptionality; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 5–6.

[844] Although by October 2013 funding decisions will be decided by CCGs, resource allocation considerations will continue to involve claims for exceptional case funding. As CCGs do not operate at arm's length from patients, unlike PCTs, there is the risk that treatment choice and personalised health care policies will increase the pressure on limited budgets. A return to more implicit rationing on the grounds of clinical appropriateness by GP practices is a possibility.

[845] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412 (Auld LJ).

[846] ibid; *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin)[62] (Sir Anthony Clarke MR); see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev. 1, 5–6 where the author compares Auld LJ's comments in *A,D &G* that the exceptional circumstances could be left undefined with those of Sir Anthony Clarke MR in *Rogers,* specifying that the PCT needed to envisage what the exceptional circumstances may be. The author, referring to eg *R (Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin) [6], concludes that *Rogers* has, however, been interpreted to refer to the need to envisage exceptional circumstances in general rather than in specific terms.

their decisions being vulnerable to legal dispute'.[847] Litigation in the courts since the decision in *A, D and G* is evidence of the accuracy of this conclusion, as is the fact that some PCTs have attempted to formulate a definition of what constitutes 'exceptional circumstances'.[848]

Thus, in *AC*, the Berkshire West PCT described their exceptionality case policy as considering cases which are significantly outside the normal range by comparing the patient with the cohort of patients with the same condition.[849] In the Court of Appeal, Hooper LJ added that exceptional circumstances tell the decision-maker that the number of persons who will succeed is expected to be a small minority.[850] There needs to be a comparator for something to be exceptional against, with the baseline or comparator being the cohort of people with the condition.[851] If the patient is one of the eligible group but cannot show relevant clinical circumstances by comparison with others in the group, then the case is not exceptional.[852] To define exceptional as requiring some unusual or unique clinical factor was, however, held to be unlawful.[853] Requiring uniqueness would disqualify any person automatically if he can be likened to another rather than having to be merely exceptional.[854] Exceptionality was to be interpreted in its dictionary sense of being 'out of the ordinary course' or 'unusual' or 'special' rather than in the sense of being unique.[855]

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[847] A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 14.
[848] ibid, referring to the definition of exceptional by West Sussex PCT in *Ross* [28] as 'a person or thing or case to which the general rule is not applicable' and by Barking and Dagenham PCT in *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin) [9] as 'not just "not the norm"'.
[849] *R (AC) v Berkshire WestPrimary Care Trust* [2010] EWHC 1162 (Admin) [31].
[850] *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247 [64].
[851] *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin) [9].
[852] *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin) [65], [82].
[853] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [28]; see also NHS Confederation, 'Priority Setting: Managing Individual Funding Requests' (2008) http://www.nhsconfed.org/Publications/Documents/Priority%20setting%20legal%20considerations.pdf accessed on 5 July 2012 cited by A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 25.
[854] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [79].
[855] ibid; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 16 wondering whether reference to the 'ordinary' reading of the term exceptional was an advice to PCTs to open their Oxford dictionaries and apply the dictionary definition.

This still leaves some ambiguity to the term exceptionality, as it will of course always be possible for other patients to emerge who are appropriately comparable. It will depend on how wide the group label is drawn.[856] How unusual or special does a patient wanting to avail himself of publicly funded CAM have to be to qualify? What is an exceptional case to qualify for treatment not generally available from a PCT?[857] Are requests by more than one patient for a particular treatment always automatically excluded from consideration as being a case for a service development rather than individual funding requests?[858]

The chapter discusses the exceptionality factors drawn from judicial review cases which are divided into funding requests for the treatment of life-threatening conditions, mainly involving novel cancer drugs, and funding requests for low-priority treatments for non-life-threatening conditions. Although there are many similarities regarding the criteria for judging cases as exceptional between these two groups, the differences justify a separate discussion of the cases.

4.3.1 Exceptionality criteria in funding requests for the treatment of life-limiting conditions

Due to a considerable number of very expensive novel cancer drugs becoming available in the recent past, health authorities have come under increasing pressure by patients to exercise their discretion and fund these drugs on an exceptional case basis. These drugs had either not yet been approved by NICE or had been rejected

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[856] It will be more difficult to show exceptionality if the cohort is a large heterogeneous group of people as in *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin) [42] and see discussion of the case below.

[857] This raises the question as to whether for every treatment there must be a possible exceptional case; see general comments in A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 27–8 posing the question, in the context of funding of expensive cancer drugs, whether PCTs would have to envisage exceptional circumstances even for drugs and therapies for which there is little evidence of benefit.

[858] This chapter does not discuss multiple requests for a treatment which is managed through in-year service developments, effectively a group of IFRs relating to a drug or treatment not generally funded, which involve commissioning a new service or modifying a service during a financial year and is an investment decision of a PCT outside the existing annual contracts, see Department of Health, 'Defining Principles for Process Supporting Local Decision Making about Medicines' (2009) http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093433.pdf accessed on 6 June 2012.

by NICE as not being cost-effective. The judgments show the significance the courts attach to the relevance of the factors and the weight attached to them in the decision-making by health authorities, together with the need to justify any refusal of treatment to avoid invalidation of the decision. The judgments, however, also point to inconsistency in the interpretation of exceptionality in funding requests for novel cancer drugs.

Rogers[859] was the first in a series of exceptionality review decisions concerning such drugs where the claimant was refused treatment. The claimant suffered from stage I breast cancer and asked to be given Herceptin, a drug suitable for patients who test positive for HER2. However, Herceptin had not been licensed for the indication of early-stage breast cancer, and the policy of the PCT was not to fund off-licence drugs, although where the patient had a healthcare problem that presented an exceptional need for treatment her case would be considered on individual merits.[860] It did not consider Mrs Rogers to be an exceptional case as she was in the same situation as all other HER2-positive women with stage I breast cancer. Her application for judicial review was rejected at first instance, but the decision was overturned on appeal. The Court of Appeal held that the PCT had acted irrationally, as its policy in clinical terms did not allow for any exceptional circumstances. The PCT, in an attempt to comply with a guidance by the Secretary of State,[861] had decided that the cost of Herceptin should be disregarded. While claiming that the decision was not based on resource constraints, the PCT had not been able to identify any clinical circumstances which would distinguish between patients. The clinical needs of all women with early stage HER2-positive breast cancer were the same. As Syrett points out, the downfall for the PCT was as a result of its decision not to treat resources as an issue when formulating its policy. Thus, 'once financial considerations had been deemed irrelevant, the PCT was to be taken as possessing

[859] *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin).
[860] ibid [22].
[861] ibid [27]; NHS Chief Executive Bulletin (294) 2005; see also generally C Newdick, 'Judicial Review: Low Priority Treatment and Exceptional Case Review' (2007) Med L Rev 236, 238–39.

available funding for *all* eligible women for whom Herceptin had been recommended by their clinician.'[862] Accordingly, if the PCT had argued scarcity of resources as a relevant consideration, '[it] would have possessed wide discretion to take account of factors other than clinical need in determining which patients should receive priority as exceptional cases.'[863] For example, it could then also have taken account of personal and social characteristics, such as whether the woman had a disabled child she needed to care for, and could make the difficult choice 'to fund treatment for a woman with a disabled child but not a woman in different personal circumstances'.[864] This might well constitute the recognition of the role of the carer in society rather than an unwarranted discrimination on the basis of some other personal characteristics.[865]

Care responsibilities were also mentioned in the case of *Gordon*[866] as a possible factor to show exceptional circumstances.[867] Mrs Gordon suffered from terminal metastatic lung cancer which was beyond treatment with surgery or conventional chemotherapy. Standard practice at this stage was best supportive care, although a new drug, Tarceva, while licensed for this indication, was not funded by the PCT and NICE approval had not been given. She had obtained private funding for four weeks' treatment privately and sought another four weeks' treatment to be funded by the PCT. The PCT's exceptional funding review had rejected her application, deciding that she was not an exceptional case. The patient applied for judicial

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[862] K Syrett, 'Opening Eyes to the Reality of Scarce Health Care Resources? *R. (on the application of Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health*' (2006) PL 664, 666.
[863] Ibid 670 cf *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin) excluding non-clinical factors from exceptionality review.
[864] *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin) [77] (Sir Anthony Clarke MR); see also C Newdick, 'Judicial Review: Low Priority Treatment and Exceptional Case Review' (2007) Med L Rev 236, 240 where the author raises the question whether exceptionality defined in such terms does not encourage inequity of access to NHS care: 'Is it reasonable for public policy to regard single people as less likely to be "exceptional" on the ground that they do not have dependants?'; see also C Newdick, 'Exceptional Circumstances – Access to Low Priority Treatments after the Herceptin Case' (2006) Clin Ethics 205, 207.
[865] J Bridgeman, '"Exceptional" Women, Healthcare Consumers and the Inevitability of Caring' (2007) Feminist Legal Studies, 235, 243–44.
[866] *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin).
[867] cf *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin) excluding non-clinical factors from exceptionality review.

review, claiming that the PCT was in fact operating a blanket exclusion of all candidates from the use of Tarceva as a third-line treatment. The court referred the matter back for reconsideration because the PCT had not considered the existence of exceptions and there had been a lack of transparency of the reasons for the original decision.[868] Ousley J stressed that Mrs Gordon may find it impossible to challenge a further refusal of funding if the PCT grappled with the relevant issues.[869] The PCT may well conclude that the drug would not be funded because of insufficient routine clinical benefit.[870] Demonstrating a greater likelihood to benefit from treatment than many others did not mean that Mrs Gordon had to be treated as an exception. The PCT could legitimately conclude that it would not fund the treatment because of the limited survival benefit to her and the limited resources available to the PCT.[871] Short-term prolongation of survival may, however, constitute exceptional circumstances, for example where someone needed to make care arrangements for young children, but this was not applicable in this case.[872]

In contrast, the increased likelihood of benefiting from the drug in question was considered a relevant factor for the determination of exceptionality in the later case of *Otley*.[873] The claimant suffered from metastatic colorectal cancer, and again all treatment such as surgery and conventional chemotherapy had been exhausted. The patient financed five cycles of the biological drug Avastin privately. This treatment was well tolerated by her and appeared to reduce the tumour size. The claimant then applied for funding from her PCT on an exceptional case basis which was, however, refused since the panel argued other treatment was available to her. Mitting J held that the panel had acted irrationally and that her case was exceptional. Although the exceptional case policy of the PCT was entirely rational and sensible, its application to this case was not so. The panel had not taken into account the slim but important

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[868] *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) [43]; C Newdick, 'Judicial Review: Low Priority Treatment and Exceptional Case Review' (2007) Med L Rev 236, 241.
[869] *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) [44].
[870] ibid [39].
[871] ibid [40].
[872] ibid [41].
[873] *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin); A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 20–21.

chance that the drug could prolong the patient's life by more than a few months, that there were, in practice, no other treatments available to her, and that on any fair-minded view of the panel's exceptionality criteria her case was exceptional.[874] She was young and fit and had responded well and without major side-effects to Avastin.[875] In addition, the judge also found that the allocation of resources is not capable of being the decisive factor when making a funding decision and only small sums are involved;[876] the cost of five cycles amounted to approximately £6,000.[877] Thus:

> The policy properly provides that the allocation of resources is an element in every decision of this kind. But the course proposed … was at least in its initial stages a course which required the allocation of only relatively small resources. [The] proposal was for four or five cycles of treatment … The course proposed … did not on any reasonable view require this Trust to put at risk the interests of other patients or, in the words of its own policy on difficult decisions, require it 'to consider the impact of funding on the health of the whole population'.[878]

The further case of *Murphy*[879] underlines the fact that when exercising their discretion PCTs must consider all exceptional circumstances of the claimant in their totality, rather than individually. In this case, a patient had developed a serious drug reaction to interferon which she received for her kidney cancer. Her consultant oncologist had applied to the PCT to fund the novel cancer drug Sunitinib on an exceptional case basis. The PCT, however, refused funding, but its refusal was

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[874] *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin) [26].
[875] ibid [19]–[21].
[876] ibid [27]; E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn OUP 2009) 86; cf *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) [10] where the likely cost was £1,500 for one month plus the cost of further months *if* the one-month treatment was found to be effective. Interestingly, the judge directed the PCT to provide treatment for the patient pending its re-consideration of the case so that the issue of scarce resources in practice was not important at least for the first month.
[877] *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin) [3].
[878] ibid [27] (Mitting J).
[879] *R (Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin).

challenged on the basis that the decision was irrational. The patient argued seven specific factors as relevant to the question whether the drug should be made available to her including, for example, that she was unable to take part in a trial with Sunitinib because she also suffered from breast cancer, that due to the adverse reaction to interferon she had not been able to take the maximum effective dose, and that despite her serious illness she remained the principal carer of her husband who suffered from a number of difficult medical conditions. The panel considered each and every one of the seven factors but concluded that none was exceptional. The court quashed the decision and remitted the case back to the PCT because, although the panel had considered the factors individually, they had not looked at them together. As Burnett J held, 'there are many factors which on their own might be sufficient to persuade a decision-maker to exercise a discretion exceptionally … But having looked at all factors individually it seems to me it is necessary to consider them in the round …'[880] If the judge had been satisfied that the panel would come to the same decision if it looked at all the circumstances together, he would have refused the application.

In *Ross*,[881] the claimant, who suffered from multiple myeloma, challenged the decision of the PCT not to fund the new cancer drug Lenalidomide on an exceptional case basis. Previous treatment with other drugs, in particular Thalidomide, had to be stopped because of the side-effect of severe peripheral neuropathy experienced by the patient. The only alternative open to the patient was Lenalidomide, which does not cause this adverse reaction. Grenfell J stated that he found against the PCT on the ground of *Wednesbury* unreasonableness in 'that the decision of the PCT was one which no reasonable authority could have made on the application before it',[882] and he subjected the decision to more intense or anxious scrutiny because the claimant's life was at stake.[883] The PCT's policy was not only unlawful, as it was not a policy for exceptional cases because the patient had to show in effect that he

[880] *R (Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin) [31].
[881] *R (Ross) v West Sussex Primary Care Trust* [2008] EWCH 2252 (Admin).
[882] ibid [94].
[883] ibid [39].

was unique and could not be likened to another, the PCT had also made a mistake of fact in its understanding of the clinical effectiveness of Lenalidomide and the meaning of cost-effectiveness in the context of exceptional cases.[884] The misunderstanding of the effectiveness of Lenalidomide had made it impossible for the PCT to assess the cost-effectiveness rationally.[885] The claimant had sought four cycles of treatment, with the potential of more cycles only if the treatment was effective; if he did not respond, the treatment was unlikely to be continued, so that further costs would not arise.[886] The PCT had also not taken into account the saving of not having to provide the expensive previous treatment to which the claimant had developed intolerance.[887] Although the PCT had considered the issue of clinical and cost-effectiveness, the court went further, delving into the substance of these factors.[888]

The need to have an exceptional case policy does not only apply in the context of expensive cancer drugs for life-threatening conditions, however, but also in the context of treatments generally considered to be of low priority by PCTs. The definition of low-priority treatments and the factors which have been considered relevant in these exceptionality decisions will be considered next.

4.3.2 Exceptionality and low-priority treatment

Low-priority treatments have been defined by Newdick as 'luxury' care or 'too peripheral to the objectives of the NHS to deserve treatment'.[889] They could also be

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[884] But see A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 28 n138 arguing that assessing the clinical effectiveness of new treatments is a challenge for exceptional case panels, as little evidence of treatments tends to be available in early clinical use.

[885] *R (Ross) v West Sussex Primary Care Trust* [2008] EWCH 2252 (Admin) [91].

[886] ibid.

[887] ibid.

[888] See ibid [85] where the court probed into the absolute survival rates in randomised controlled studies of patients on Lenalidomide and patients in the control group, and also looked at median survival advantage figures while assessing whether the PCT had understood these figures and taken them into account.

[889] C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 307 cf R Klein and H Sturm, 'Viagra: A Success for Rationing?' (2002) Health Affairs 177, 184 arguing that the distinction between medically necessary and lifestyle interventions may be arbitrary if the aim of medicine is to improve quality of life. If psychological distress is put on a par with physical pain, people's ability to conform to societal norms from having children (IVF), to having bodies of an

defined as treatments for non-life-threatening conditions or treatments of low clinical value.[890] Different PCTs have nominated different treatments as low-priority, ranging from surgery for varicose veins, hair transplantation, face lifts, tattoo removal, vasectomy, circumcision, bariatric surgery, tonsillectomy, knee arthroscopy, IVF, breast augmentation, gender reassignment surgery, to complementary alternative medicine including homeopathy.[891] Such treatments have been described as falling in the lowest 10% in terms of priority of treatment and would therefore only be provided in cases of overriding clinical need.[892] The relevant factors considered in cases of low-priority treatment can be distinguished from those considered in cases of treatment for life-limiting malignancies and are also given different weight in the decision-making. The case law again demonstrates the ambiguity of the exceptionality factors in play.

Exceptionality criteria in IFRs for low-priority, non-life-threatening conditions

In the case of *A, D and G*,[893] the applicants, who suffered from gender identity dysphoria, applied for judicial review of the PCT's refusal to pay for their

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acceptable shape and appearance (cosmetic surgery and treatment for obesity) then the distinction becomes even more blurred. Thus lifestyle or luxury treatment is an 'overelastic hold-all. What such treatments appear to have in common is that they are defined by consumer demand and not by technical medical criteria or a medical definition of *appropriateness*.'

[890] PCTs have been expanding the list of treatments they do not generally fund. Some PCTS have targeted over 100 such treatments whereas other lists are more modest and although there is some consistency between the various lists, it is estimated that overall 250 such treatments have been identified, see Audit Commission, *Reducing Spending on Low Clinical Value Treatments* (Audit Commission 2010) 5; see also J Maybin and R Klein, *Thinking about Rationing* (King's Fund, London 2012) 21 stating that more than a third of PCTs had expanded the number of treatments for which they were withholding funding in 2011, http://www.audit-commission.gov.uk/SiteCollectionDocuments/Downloads/20110414reducingexpenditure.pdf accessed 30 September 2012.

[891] eg *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA); see eg the Kent and Medway referral and treatment criteria document lists acupuncture, chiropractic therapy, herbal remedies, homeopathy, osteopathy etc. as low-priority treatments not routinely funded, http://www.westkentpct.nhs.uk/NetsiteCMS/pageid/24/index.html accessed 30 October 2012; see also the 'Croydon List of Low Priority Treatments' in Audit Commission, *Reducing Spending on Low Clinical Value Treatments* (Audit Commission 2010) appendix 1, http://www.audit-commission.gov.uk/SiteCollectionDocuments/Downloads/20110414reducingexpenditure.pdf accessed 30 September 2012.

[892] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 402.

[893] ibid 399.

transsexual surgery because of its policy not to fund such treatment in the absence of 'overriding clinical need or other exceptional circumstances'. In 1995, the health authority had adopted a policy allocating low priority to treatments which it considered to be clinically ineffective, in the sense of achieving no or little clinical gain. The PCT's avowed policy was described as providing effective healthcare, in the sense of 'medically effective' healthcare.[894] Specifically, it stated in its policy:

> a wide variety of medical procedures currently in use within the NHS cannot be demonstrated in research trials to have any clinical effectiveness. The NHS Executive has, therefore, urged health authorities to reallocate purchasing priorities to promote the use of more effective treatments at the expense of those which are of no proven benefit.[895]

To the medical effectiveness criterion, the health authority later added the criterion of appropriateness for public funding. The policy was held to be unlawful, in part because the PCT refused to recognise the effectiveness of the treatment for gender identity dysphoria despite 'a strong and respectable body of medical opinion' to the contrary.[896] The PCT had argued that the effectiveness of the treatment had not been subjected to randomised controlled trials, and that research conducted was likely to be biased and did not indicate the long-term results of surgery. For Auld LJ, the PCT's argument of the lack of effectiveness, despite the existence of medical opinion supporting surgery, was not relevant. The authority had accepted transsexualism as an illness and therefore should 'accord the condition a place on the scale of its priorities for illnesses instead of relegating it to the outer regions of conditions which it plainly does not so regard'.[897] Buxton LJ, on the other hand, engaged with the effectiveness argument, concluding that there was no need to submit a respectable body of opinion in favour of gender reassignment surgery to

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[894] ibid 404.
[895] ibid 408.
[896] Ibid 412; C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 105, K Syrett, *Law, Legitimacy and the Rationing of Healthcare* (CUP 2007) 173.
[897] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 408.

research trials.[898] In addition, where such evidence exists, 'it is not open to a rational health authority simply to determine that the procedure has no clinical benefit while giving no indication why it considers that is so'.[899] 'Since the authority did not regard gender reassignment surgery as an effective form of treatment for transsexualism it would in practice be impossible for an individual to make out a case for such surgery, even if an overriding clinical need was successfully established.'[900] In effect, therefore, the authority was operating a 'blanket policy' which failed to admit of exceptions whereas the degree of consideration required by the decision-maker also depended on the importance of the interest of the citizen affected by the decision.[901]

An earlier case which turned on the question of effectiveness, or the likelihood of success of a treatment and the weight to be attached to conditions which did not amount to 'critical illness', was the earlier case of *R v Sheffield Health Authority, ex p Seale*.[902] The court held that a ban on women over 35 receiving IVF treatment was justified, on the grounds that the chances of achieving a pregnancy decreased in women over that age, and the application failed. However, the case may not be good law. Rather than considering each case on its merits and allowing for exceptional circumstances, Auld J stated it was not unreasonable *not* to consider each case individually where the case did not involve a 'critical illness':

> [A] clinical decision on a case by case basis is clearly desirable and, in cases of critical illness, a necessary approach … However, … I cannot say that it is absurd for this authority, acting on advice that the efficacy of this treatment decreases with age and that it is generally less effective after the age of 35, to

[898] ibid 404.
[899] ibid 412.
[900] K Syrett, '*R v. North West Lancashire Health Authority, ex parte A, D and G* [1999] Lloyd's Rep Med 399' (2000) Journal of Social Welfare and Family Law 200, 202.
[901] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412; C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 107.
[902] *R v Sheffield Health Authority, ex p Seale* (1994) 25 BMLR 1.

> take that as an appropriate criterion when balancing the need for such a provision against its ability to provide it …[903]

As Newdick points out, it is unlikely that applications for transsexual surgery demand greater scrutiny than applicants wanting IVF, as blanket bans will more likely only be upheld where evidence of inefficacy of treatment was over-whelming.[904]

The more recent case of *AC*[905] concerned the exceptional case review of a transsexual who was seeking funding for breast augmentation surgery, rather than core gender reassignment surgery which would have been funded by the Berkshire PCT. The claimant had been diagnosed with gender identity disorder and had undergone hormonal treatment which had not led to the desired breast development. Breast surgery of transsexuals was classified by the PCT as a non-core gender reassignment procedure, and was considered, in the same way as cosmetic breast surgery or cosmetic procedures generally, as low-priority treatment. The claimant *AC* sought judicial review of the PCT policy in view of a natal female patient's success in obtaining funding for her breast augmentation surgery on an exceptional case basis. Bean J rejected the application of the transsexual claimant as not being one of exceptionality when compared to that of the natal patient. The natal patient's case was exceptional because of the severity of the psychological disorder from which she suffered due to her perceived physical shortcoming, in contrast to the mild to moderate distress suffered by *AC.* The judge also found that there was no general medical consensus on the effectiveness of breast augmentation surgery as providing considerable medical benefit to patients, whether natal or transsexual, and that the PCT had not acted irrationally in taking the view that the clinical effectiveness of the treatment in this sense was uncertain.[906] As Hooper LJ confirmed in the Court of Appeal dismissing the transsexual appellant's case, there were no exceptional

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[903] *R v Sheffield Health Authority, ex p Seale* (1994) 25 BMLR 1, 3.
[904] C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 107.
[905] *R (AC) v Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin); appeal dismissed in *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247.
[906] *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247 [30].

circumstances as there was no evidence of significant health impairment of the patient and no evidence of the intervention improving health status.[907]

The case of *Condliff*[908] considered the relevance of non-clinical factors in the determination of exceptionality. Mr Condliff, a 62-year-old retired policeman, applied for exceptional funding from his PCT for bariatric surgery, as a treatment for his obesity. He suffered from diabetes and a number of other health problems such as renal impairment, hypertension and obstructive sleep apnoea. His weight gain – he was morbidly obese with a body mass index (BMI) of 40 – was allegedly due to his treatment with insulin. Although he had attempted to lose weight using standard non-surgical methods, including dietary, lifestyle and drug therapies, it had been unsuccessful. The PCT rejected Mr Condliff's application for funding as his BMI had not reached the threshold for routine funding and his case was not exceptional. His condition deteriorated further: he became reliant on the use of a wheelchair and was housebound. His BMI had reached 43. He could no longer attend church nor could he play his guitar due to swelling and pain in his hands, and he had developed retinopathy and renal failure due to his diabetes. He also became incontinent and was unable to dress and shower himself. The second application for funding of bariatric surgery was again refused as the applicant did not meet the eligibility criteria of a BMI of 50, nor had he met the grounds for exceptionality under the PCT's policy. Mr Condliff applied for judicial review regarding the criteria set by the PCT for determining exceptionality which excluded social factors.[909] This was argued to contravene his human rights under Article 8 of the European Convention of Human Rights (ECHR). The PCT's policy stated:

> In reaching a decision as to whether a patient's circumstances are exceptional, the Panel is required to follow the principle that non-clinical or

[907] ibid [63]–[65].
[908] *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin).
[909] ibid [14].

> social factors including social value judgments about the underlying medical condition or the patient's circumstances are never relevant.[910]

According to Waksman J, Article 8 did not make it unlawful for a PCT to adopt a policy by which an individual funding request had to be determined exclusively by reference to clinical factors. Although the Strasbourg Court has recognised that Article 8 can be relied on to impose a positive obligation on the state to take measures to provide support for an individual, Article 8 rights 'are not, generally, engaged in healthcare resource allocation given the margin of appreciation afforded to states when making such decisions'.[911] 'Article 8 cannot be considered applicable each time an individual's everyday life is disrupted, but only in exceptional circumstances, where the state's failure to adopt measures interferes with the individual's right to personal development…'[912] The Social Factors Exclusion policy of the PCT did not violate Article 8 as it did not create a positive obligation in the context of an individual funding request.[913] Waksman J did, however, consider the possibility of social factors which had direct clinical implications, in contrast to non-clinical social factors.[914] Pure social factors, such as a social value judgment about smokers, an applicant's contribution to society, the value of keeping an employed person in work or a person engaged in dangerous sports, would be ruled out.[915] It is less clear what factors would constitute *clinical* social factors, although the judge cited the IFR non-discrimination policy of East Lancashire, Blackburn with Darwen PCT suggesting that factors such as a person's religion, lifestyle, social

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[910] ibid [10].
[911] *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin) [62] referring to the following Strasbourg Court decisions: *Sentges v The Netherlands* App no 20677/02 (ECtHR, 3 July 2003) where the court rejected the admissibility of an Article 8 claim to a robotic arm; *Pentiaca v Moldova* App no 14462/03 (ECtHR, 4 January 2005) where the complaint concerning the claim for medication for haemodialysis at public cost was held to be inadmissible, cf *Tysiac v Poland* (2007) 22 BHRC 155 and *X and Y v Netherlands* App no 8978/80 (ECtHR, 26 March 1985) which concerned the need for a framework to adjudicate upon and enforce Article 8 rights whereas such a framework was in existence within the NHS.
[912] *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin) [48] referring to the Strasbourg court's judgment in *Sentges v Netherlands* (application no 20677/02: 3 July 2003).
[913] *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin) [52], [54].
[914] ibid [23].
[915] ibid [24].

position, family or financial status, or intelligence might be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit. However, this leaves open the question when a social factor takes on clinical significance.[916]

Mr Condliff appealed the first instance decision unsuccessfully. The Court of Appeal held that the adoption of the IFR policy by the PCT did not contravene the Convention.[917] According to Strasbourg jurisprudence, a policy that IFRs should be determined exclusively by reference to clinical factors was not unlawful.[918] 'The Strasbourg Court had shown a strong reluctance to entertain complaints of that kind because of the difficult assessments required in the fair administration of a healthcare system with limited resources.'[919] The PCT had grappled with the difficult ethical questions involved and had struck what it considered to be a fair balance between the interests of the individuals and the community, including the question of what constitutes clinical and non-clinical factors, and between different patients with similar health conditions.[920] A PCT was entitled to set an IFR policy which reflects what it reasonably considers to be the fairest way of treating patients claiming exceptional clinical need.[921]

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[916] Arguably distinguishing patients on the basis of clinical social factors is not the same as on the basis of their personal circumstances, see eg A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 13 where the author asks, in the context of the allocation of expensive cancer drugs, whether, on the grounds of justice, it is not time to move away from the idea that some patients are exceptional on the basis of social circumstances; cf C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 309 where the author states that denying treatment to a patient whose lifestyle has made the likelihood of clinical success so small that the risk of the procedure cannot be justified by the limited benefits expected from it, may be justified on purely clinical grounds.

[917] *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWCA Civ 910 [55].

[918] ibid [51].

[919] ibid [47].

[920] ibid [47]; see also at [18] where Toulson LJ specifically mentioned that the consideration by a PCT of a patient's immobility or inability to attend to his own personal hygiene is regarded as consideration of clinical factors, but not whether he is employed or unemployed and whether he lives alone or with someone else, and at [18] that the consideration by the PCT of a treatment provided differentially to patients who were carers would tend to favour treatment for women over men.

[921] ibid [47].

Although there has not been a judicial review of refused IFRs for CAM to date,[922] there is anecdotal evidence that patients have had requests for acupuncture for lower back pain and also osteopathy for lower back pain refused by PCTs.[923] In the following the chapter examines the hypothetical situation of a health authority's decision being challenged in court by a patient demanding CAM treatment, highlighting some of the uncertainties of the definition of exceptionality criteria.

4.4. Exceptionality review and complementary alternative medicine

As has been stated, the National Health Service Act 2006[924] does not prohibit the provision of CAM under the NHS and, furthermore, section 1 of the Act provides that the Secretary of State has a duty to provide a comprehensive health service.[925] The growing popularity of CAM has led to an expansion of its use, funded both privately and within the NHS.[926] Patients unwilling or unable to pay may consider asking for funding of the treatment by their PCT to obtain the treatment under the

[922] There is variation in access to CAM between different PCTs with some PCTs providing some NHS funded CAM, see chapter 1; see also GP Online, http://www.gponline.com/bulletin/daily_news/article/1154606/pcts-abandon-funding-homeopathy/ accessed on 30 October 2012, suggesting that 15% of PCTs were providing NHS funding for homeopathy in 2011/2012.

[923] E Gkeredakis, 'Individual Healthcare Rationing : Insights from an Ethnographic Study in the English NHS', presentation on 28 February 2012 at Queen Mary University of London, commented on two cases of IFRs that were refused: Case 1: Acupuncture for back pain was refused, despite the NICE guideline on lower back pain, as the panel was directed to a literature search including systematic reviews showing that there was no evidence that acupuncture works for lower back pain. Case 2: Funding for osteopathy for lower back pain was refused because (a) the patient had already paid for private treatment and the PCT had a policy of not funding private treatment retrospectively; (b) the patient was not covered by the NICE guideline on lower back pain as he had had back pain for more than 12 months; (c) there was limited evidence of effectiveness for osteopathy for lower back pain and it may not be more effective than drugs and (d) NICE recommendations are service developments that need to be prioritised by PCTs.

[924] As amended by the Health and Social Care Act 2012.

[925] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 70; see also chapter 1.

[926] KJ Thomas and others, 'Use and Expenditure on Complementary Medicine in England: A Population Based Survey' (2001) 9 Complementary Therapies in Medicine 2, 8; see also generally S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and The State* (UCL Press 1999) 46–49.

NHS.[927] PCTs have a statutory duty to commission medical services as they consider necessary to meet the healthcare needs of the local population and must not exceed their annual financial allocations.[928]

In summary, the following principles regarding the discretionary powers of PCTs can be established from case law:

- It is a matter for the PCT how it allocates its resources, so long as it does so reasonably.[929]
- When deciding whether to fund a treatment in an individual patient's case, a PCT is entitled to take into account the financial restraints on its budget as well as the patient's circumstances.[930]
- It is within the discretion of the PCT to consider some treatments as low priority and to decline funding for these treatments save in exceptional circumstances, provided such circumstances can be envisaged.[931] PCTs cannot operate blanket bans on treatments.[932]
- Exceptionality needs to be understood in the ordinary sense of the word.[933] A patient need not show that he or she is unique in order to qualify as an exceptional case.[934]

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[927] J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 72 stating that patients are asking for CAM therapies to be made available to them under the NHS who are often unable to obtain them privately because of cost; see also KJ Thomas and others, 'Trends in Access to Complementary or Alternative Medicines via Primary Care in England: 1995–2001. Results from a Follow-up National Survey' (2003) 20 Family Practice 575, 575 stating that although GP practices increasingly offer patients access to CAM therapies, much of this is funded privately, without any corresponding increase of practices making NHS referrals for CAM.
[928] National Health Service Act 2006 s 230.
[929] *R v Cambridge Health Authority, ex p B* [1995] 1 WLR 898, 906.
[930] *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin) [58].
[931] ibid [59], [62], [65].
[932] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412.
[933] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [79].
[934] ibid.

Most PCTs do not routinely fund CAM treatments but include them on their list of low-priority treatments.[935] Patients who claim access to these low-priority treatments therefore need to demonstrate exceptional circumstances to be successful with their individual funding request.[936] At least in part to avoid costly litigation[937] PCTs will attempt to navigate the criteria that have emerged from exceptionality review cases of orthodox treatment. Although there is considerable variation in the definition of exceptionality policies amongst PCTs, many have adopted the formulation publicised by the NHS Confederation and based on case law:

> In making a case for special consideration, it needs to be demonstrated that: that the patient is significantly different to the general population of patients with the condition in question; and the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition. The fact that the treatment is likely to be efficacious for that patient is not in itself, a basis for exceptionality.[938]

As discussed, the problem for PCTs and patients alike is the ambiguity of the exceptionality criteria developed by the courts. Indeed, the NHS Confederation admits that 'the law is not yet clear as to the exact nature' of exceptionality and that

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[935] eg the Kent and Medway referral and treatment criteria document lists acupuncture, chiropractic therapy, herbal remedies, homeopathy, osteopathy etc. as low-priority treatments not routinely funded, http://www.westkentpct.nhs.uk/NetsiteCMS/pageid/24/index.html accessed 30 October 2012.

[936] A patient whose individual funding request has been refused may wish to consider an application for judicial review of the decision once he has exhausted the PCT's internal appeals procedure.

[937] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' [2010] J Public Adm Res Theory (suppl 2): i243, i251 who develop this argument in the context of the local authority public services.

[938] J Maybin and R Klein, *Thinking about Rationing* (King's Fund, London 2012) 25; NHS Confederation, 'Priority Setting: Managing Individual Funding Requests'(2008) 4, http://www.nhsconfed.org/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf accessed on 2 October 2012.

the very nature of exceptionality makes it 'impossible to anticipate every exceptional case'.[939]

4.4.1 Exceptionality criteria and CAM treatment

With this lack of certainty of any exceptionality policy in mind, health authorities will be driven by values such as the consistency, fairness and equity of the decision-making and most PCTs will have general decision-frameworks to this effect.[940] They will attempt to reconcile the tensions between the needs of the many and the claims of the individual while being concerned with fidelity to the law.[941] When deciding on funding any low-priority treatment on an exceptional case basis the factors a PCT will take into account will clearly depend on the individual situation of the patient. According to the case law, only clinical factors or social factors with clinical implications need to be assessed by PCTs in the determination of a patient's exceptionality.[942] However, many of the clinical factors which emerge from case law and are appropriate for judging a case as exceptional[943] remain in general terms and are difficult to interpret, particularly in the context of low-priority, non-life-threatening treatment. Thus, a health authority ought to consider:

- Whether the patient demonstrates overriding clinical need.[944]
    - However, does the need depend on the severity or acuteness of the condition? Does the need depend on the length of the patient's expected survival?

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[939] NHS Confederation, 'Priority Setting: Legal Considerations' (2008) http://www.nhsconfed.org/Publications/Documents/Priority%20setting%20legal%20considerations.pdf accessed on 2 October 2012.

[940] See eg *R (Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin) [8] and *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) [3].

[941] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' [2010*J* J Public Adm Res Theory (suppl 2) i243, i247 referring to the ethos of the public service.

[942] *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWCA Civ 910 but see also n 916 and text to n 916.

[943] See also factors drawn from case law in the context of funding requests for novel cancer drugs in A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 23.

[944] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412; *R (Rogers) v Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWCA Civ 392 (Admin) [62].

- Whether the patient has exhausted conventional treatments.[945]
    - Is this a relevant factor for patients wanting low-priority treatments or only for patients requiring novel cancer drugs?
- Whether the patient is intolerant of, or hypersensitive to conventional treatment.[946]
    - Would this factor also apply to a patient requesting CAM and complaining of severe side-effects from orthodox treatment?
- Whether he has previously benefited from the particular therapy, possibly if the patient has purchased it privately, since this consideration would be part of the patient's specific clinical history and prognosis.[947]
    - How long would the prolongation of survival have to be to constitute a sufficiently good prognosis? Is the prognosis of the patient relevant where he suffers from a long-term chronic condition rather than from a cancer with a short life expectancy?
- Whether he is likely to benefit from treatment more than others.[948]
    - However, can the likelihood to benefit ever be defined objectively?

With regard to the clinical benefit for a particular patient of the requested treatment, PCTs will need to consider the effectiveness and cost-effectiveness of the treatment generally. In the context of CAM treatment, it is these factors that may represent major stumbling blocks in the exceptionality assessment. Both these factors are singled out for more detailed discussion.

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[945] *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin).
[946] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [76].
[947] E.g. *R (Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin) [20] cf *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin).
[948] *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247 [54]; cf *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) [39] where Ouseley J opined that greater clinical benefit to the applicant does not necessarily make her case exceptional; see also C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 312–14 where the author makes the valuable point, albeit in the context of futile treatment, that that clinical benefit is not an absolute notion and opportunity costs need to be considered.

The criteria of clinical effectiveness and cost-effectiveness

From judicial review cases of funding requests for novel cancer low-priority treatments, the following principles can be formulated regarding the consideration of effectiveness and cost-effectiveness in the determination of exceptionality by a health authority. Again many of the legal pronouncements remain in very general terms or are open to various interpretations. Thus:

- In reaching a decision, the health authority should consider the nature and seriousness of each type of illness and the effectiveness of various forms of treatment.[949]
- A decision which seriously affects the citizen's health will require substantial consideration and will be subject to careful scrutiny by the court.[950]
- A health authority cannot simply determine that the procedure has no proven clinical benefit while giving no indication of why it considers that is so.[951]
- A health authority may not simply dismiss responsible medical opinion, even if there are differing opinions on the effectiveness of a treatment. Such opinion is relevant and must be given proper weight.[952]
- The health authority needs to understand the clinical efficacy data and the quality of the evidence.[953]
- Where there are differing opinions on clinical effectiveness and the health authority's conclusions are not irrational, the court will not decide which opinion is right.[954]

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[949] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 413 and *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [34].
[950] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412 and *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [39].
[951] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412.
[952] ibid.
[953] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [84], [85].

- A health authority needs to understand the effectiveness data in order to be able to assess cost-effectiveness.[955]

Effectiveness and, consequently, cost-effectiveness are of course not absolute notions. Scientific evidence will often be insufficient to provide clear conclusions as to the benefits of a particular treatment in biomedicine.[956] This problem for the PCT's exceptionality assessment is magnified when considering CAM treatment modalities which are assessed for their effectiveness and cost-effectiveness within the dominant healthcare system.

The problem of the proof of effectiveness

Orthodox medicine and CAM represent two treatment paradigms[957] with diverging views of the meaning of 'effectiveness'. Orthodox medicine is generally regarded to be evidence-based medicine (EBM), i.e. what Sackett terms 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'.[958] EBM has been enthusiastically promoted within the NHS, with reliance on research evidence rather than clinical judgment as the major concern.[959] However, Sackett includes in the definition of EBM the integration of clinical expertise with the best available external clinical evidence from systematic research.[960] Provision of CAM treatment is contested because of the perceived or

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[954] *R. (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 [31]; *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [36]; *R (Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin) [6]; *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247 [22], [23].
[955] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [91].
[956] C Newdick, 'Resource Allocation in the National Health Service' (1997) 23 Am J L & Med 291, 313 stressing that evidence may be incomplete, ambiguous or uncertain; A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 28 and n138; see also generally, R Veatch, *Patient, Heal Thyself: How the New Medicine Puts the Patient in Charge* (OUP 2009) chapter 3.
[957] MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 2–3; see also chapter 1.
[958] D Sackett and others, 'Evidence-Based Medicine: What It Is and What It Isn't' (1996) 312 BMJ 71.
[959] L Wye and others, 'Patient Choice and Evidence Based Decisions: The Case of Complementary Therapies' (2009) 12 Health Expectations 321, 323.
[960] D Sackett and others, 'Evidence-Based Medicine: What It Is and What It Isn't' (1996) 312 BMJ 71 defining individual clinical expertise as the 'proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice'; see also H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 86 arguing that this 'tacit' knowledge or

actual lack of research evidence.[961] Because of the opposition to CAM, at least partly due to the political influence of evidence-based medicine,[962] resources are directed by government and health funders towards the areas of health where evidence can be demonstrated and away from interventions which have not been shown to be effective.[963] Therefore, as Stone argues, 'evidence-based healthcare has an inherent bias against therapeutic interventions in which outcomes cannot be adequately measured or easily defined.'[964] Whereas orthodox medicine gauges the success of treatment with reference to the alleviation of symptoms,[965] how to measure the success or lack of success of treatment is a major issue for many CAM modalities.[966] For a health authority's assessment of an individual funding request the lack of scientific validation of efficacy of the desired CAM therapy is therefore likely to present a considerable obstacle.[967] Although PCTs can examine the

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the 'intuition of professionalism', together with reliance on rigorous scientific method, serves to nullify or fend off claims of outsiders.

[961] J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn, Routledge 2002) 113; KM Boozang, 'Western Medicine Opens the Door to Alternative Medicine' (1998) 24 Am J L & Med 185, 204.

[962] J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn, Routledge 2002) 113; H Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship* (OUP 1994) 86–88; S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 136–39.

[963] C Ham, *Health Policy in Britain* (6th edn Palgrave Macmillan 2009) 273; see also Chapter 1, Definitions of Health.

[964] J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn Routledge 2002) 113.

[965] ibid 13.

[966] Most CAM treatment is used for chronic, long-term conditions which are not necessarily life threatening but may affect the patient's quality of life considerably, see generally E Ernst and others, *The Desktop Guide to Complementary and Alternative Medicine: An Evidence-Based Approach* (2nd edn, Mosby Elsevier 2006); S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 32–33. While these conditions are not generally amenable to a cure by orthodox medicine CAM is claimed to provide subjective symptom relief and not merely a favourable and scientifically measurable clinical outcome, see MH Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press 1998) 4.

[967] When considering the clinical effectiveness of treatment, valid evidence has to be derived by synthesising the available evidence from research. Sound evidence which can be relied on to classify an intervention as effective or ineffective is derived from studies which are conducted in a way that is held to be 'scientific'. A hierarchy of evidence is used which defines the scientific soundness of the research, with randomised controlled trials (RCTs) representing the gold standard. In an RCT, patients are allocated randomly between groups, with the control group receiving placebo, no treatment, or existing conventional treatment. Ideally, RCTs should be double-blind, which entails

evidence about treatments and services they commission themselves they may also look to NICE for guidelines on the use of CAM for specific conditions.[968]

NICE guidelines on CAM

Although NICE has never carried out a health technology appraisal on CAM, so that there has never been mandatory positive guidance on the use of CAM in the NHS,[969] it has evaluated CAM treatments when developing standards for non-mandatory clinical guidelines for the treatment of specific conditions.[970] The Department of Health expects NICE guidance to be implemented consistently across the NHS,[971] so PCTs should take steps towards the implementation and funding also of non-mandatory NICE clinical practice guidelines.[972]

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that neither the clinician nor the patient knows which treatment the patient is receiving. Other research evidence is considered lower in the hierarchy of evidence, such as non-randomised studies, descriptive studies, or opinions of respected authorities, where the validity may be doubted on the grounds of bias, see S Harrison, 'The Politics of Evidence-Based Medicine in the United Kingdom' (1998) 26 Policy and Politics 15, 20; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 28 n138 pointing to the problem of the assessment of evidence of clinical trials by PCTs in the context of orthodox treatment for cancer; see also J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn, Routledge 2002) 113; KM Boozang, 'Is the Alternative Medicine? Managed Care Apparently Thinks So' (2000) 32 Conn L Rev 567, 586 arguing that the need for evidence-based practice tends to operate against CAM because many therapies have not been subjected to RCTs. Furthermore there are significant practical or methodological problems which hinder scientific CAM research, see J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn, Routledge 2002) 115.

[968] N Freemantle, 'Dealing with Uncertainty: Will Science Solve the Problems of Resource Allocation in the UK NHS?' (1995) 40 Soc Sci Med 1365, 1365.

[969] eg E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350.

[970] ibid 1350–56 discussing the evaluation of 65 guidelines on the NICE website in August 2009 for references to CAM, of which 17 mentioned some form of CAM .

[971] K Syrett, 'NICE Work? Rationing, Review and the "Legitimacy Problem" in the New NHS' (2002) 10 Med L Rev 1, 2 fn 9, referring to Department of Health, *A First Class Service: Quality in the New NHS* (HMSO 1998) para 2.26; see also C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 210 stating that PCTs may feel constrained to adopt a discretionary clinical guideline due to political pressure to implement guidelines such as for IVF treatment; cf H Mooney, 'Two Thirds of Primary Care Trusts Are Cutting Referrals, Shows Survey' (2011) BMJ 343 arguing, that due to current cuts in PCT funding, 64% of PCTs have restricted referrals for low-priority treatments including IVF treatment.

[972] The need for treatment to be evidence-based is official policy for the NHS, see S Harrison, 'The Politics of Evidence-Based Medicine in the United Kingdom' (1998) 26 Policy and Politics 15, 15. NICE was created to encourage evidence-based practice by providing the NHS in England and Wales with authoritative, robust and reliable guidance on current best practice, see NICE, *A Guide to Our Work* (NICE 1999), Introduction. The reliance on scientific evidence is thought to have the advantage of

Four possible scenarios with regard to clinical practice guidelines and the assessment of a specific CAM modality can be envisaged, which need to be considered in turn.

Scenario 1: Where the evidence of effectiveness of a particular CAM modality is ambiguous or the NICE recommendations are neither favourable nor unfavourable,[973] a PCT will be able to use the NICE findings in rationalising its refusal of CAM treatment to a patient. As long as the PCT can show that it has considered and understood the data and the quality of the evidence[974] and has explained the reasoning for its refusal,[975] the court is unlikely to demand a reconsideration of the case on the basis of this factor.

Scenario 2: The same principles will apply where the NICE recommendations are unfavourable.[976] A refusal of an IFR is unlikely to be referred for reconsideration by the court, even if some effectiveness data can be adduced.[977]

Scenario 3: Where there is a favourable NICE clinical practice guideline about the effectiveness of CAM in a specific condition, the refusal of treatment will be more difficult to justify by the PCT. Examples of NICE clinical guidelines pointing to

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enabling resources to be freed from ineffective treatments while also helping to reduce inappropriate variation in clinical practice and unequal access to treatment, so-called post-code prescribing, see K Syrett, 'NICE Work? Rationing, Review and the "Legitimacy Problem" in the New NHS' (2002) 10 Med L Rev 1, 3 fn 16, referring to A First Class Service, para 2.11; cf C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 208 arguing that postcode prescribing is inevitable absent any central guidance as disinvestments from other areas will take place to accommodate mandatory NICE guidance; see also chapter 1 and the discussion of the value of equity of access.

[973] An example would be use of acupuncture in opioid detoxification, see E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350, 1352.

[974] *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 1908 (Admin) [84], [85].

[975] *R v North West Lancashire Health Authority, ex p A, D and G* [1999] Lloyd's Rep Med 399 (CA) 412.

[976] See eg E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350, 1350–56: the NICE recommendation of homeopathy is unfavourable for chronic heart failure, obesity, chronic fatigue syndrome and rheumatoid arthritis; see also House of Commons, *Report of the Science and Technology Committee*, *Evidence Check 2: Homeopathy* (HMSO 2010).

[977] An example would be massage and relaxation for depression where some efficacy data exists, see E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350, 1352.

positive evidence of effectiveness are for reflexology for multiple sclerosis, exercise therapy for chronic fatigue syndrome, hypnotherapy and/or psychological intervention for irritable bowel syndrome, acupuncture or spinal manipulation for non-specific low back pain.[978] However, even in such a situation, if the PCT can show that there are differing opinions about the clinical effectiveness,[979] the court will not decide which opinion is right as long as the health authority's conclusions are not irrational[980] and it gives proper weight to the differing opinions.

Scenario 4: In conditions where NICE has not evaluated CAM at all, or has omitted part of the available evidence on CAM in its recommendations,[981] but evidence of the effectiveness of some CAM modalities is available,[982] the PCT may still be able to demonstrate that there are different opinions concerning the effectiveness of the CAM treatment in question and that its conclusions as to the lack of efficacy are not irrational in order for the court not to order a reconsideration of the case.

Where the evidence of effectiveness of a CAM modality in a particular condition is unambiguous – although this will not often be the case – the cost-effectiveness factor will be an additional relevant consideration in the PCT's assessment of exceptionality. Of course, cost-effectiveness data are only relevant once the effectiveness of a treatment has been established. However inexpensive a treatment, it makes little sense to provide it if there is no proof that it is effective because of the opportunity costs involved, i.e. the range of 'opportunities that will be foregone if

[978] ibid 1351–56.
[979] See ibid 1354–56 stressing that the evidence of effectiveness of hypnotherapy and/or psychological intervention for irritable bowel syndrome and for acupuncture or spinal manipulation for non-specific low back pain is neither strongly positive nor strongly negative; see also case 1 described in n 923.
[980] *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) [31]; *R (AC) v Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin) [22], [23], approved in *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247 [30].
[981] E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350.
[982] Examples would be stroke and hypertension where some CAM modalities are effective see E Ernst, 'Assessment of Complementary and Alternative Medicine: the Clinical Guidelines from NICE' (2010) J Clin Pract 1350, 1356–58.

the money to pay for them is diverted elsewhere'.[983] If a CAM modality cannot conclusively be shown to work or be validated scientifically, its cost-effectiveness must remain in doubt.[984]

Considerations of cost-effectiveness

Cost-effectiveness analysis, unlike effectiveness which does not compare different treatments for different conditions, provides 'a lowest common denominator concept in terms of which the *outcome* of any intervention may be assessed and provides the unit costs of producing such outcomes'.[985] One of the methods of achieving this outcome measure is the Quality-Adjusted Life Year, or QALY, used by NICE in its cost-effectiveness assessments.[986] Problems become apparent when the QALY cost-effectiveness analysis is applied to CAM.

Firstly, one of the difficulties in making a QALY assessment[987] and calculating a cost per QALY is the need to know the overall cost of the treatment. The costs of many CAM treatments are, however, difficult to calculate as treatment tends to be long term so that costs are often simply estimates.[988] Secondly, as CAM therapies generally do not claim a curative or a life-extending effect, it is the quality of life

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[983] C Newdick, *Who Should We Treat?* (2nd edn, OUP 2005) 21 and 27.
[984] See generally J Stone and J Matthews, *Complementary Medicine and the Law* (OUP 1996) 73.
[985] S Harrison, 'The Politics of Evidence-Based Medicine in the United Kingdom' (1998) 26 Policy and Politics 15, 24.
[986] See also chapter 1.
[987] There are a considerable number of problems with the QALY measure which cannot be discussed here, see e.g. J Harris, 'QALYfying the Value of Life' (1987) 13 J Med Ethics 117.
[988] Few studies concerning the costs of CAM have been published, see eg KJ Thomas and others, 'Use and Expenditure on Complementary Medicine in England: A Population Based Survey' (2001) 9 Complementary Therapies in Medicine 2, 8 where the authors conclude that the total NHS expenditure on CAM in 1998 amounted to an estimated £55.9 million based on an estimated 2.31 million client visits, but the costs were based on an extrapolation of the number of visits to CAM practitioners by patients privately, the reported cost of the most recent visit and the estimated percentage of visits provided by the NHS. The study also only included a limited number of CAM modalities. An additional problem is that much of CAM is used in addition to orthodox treatment so that its use leads to additional costs rather than savings, according to a review of the cost-effectiveness of CAM, see PH Canter and others, 'Cost-Effectiveness of Complementary Therapies in the United Kingdom – A Systematic Review' (2006) eCAM 3(4) 425, 432 where the authors, however, found a favourable cost per QALY comparison with orthodox treatments where there was a direct comparison of treatment costs, although the effectiveness of the complementary therapies for the indications investigated was uncertain.

improvement[989] which is relevant in the QALY calculation of a CAM treatment.[990] However, the QALY framework gives precedence to life-extending treatments over quality of life improvements. The life expectancy before and after treatment, part of the QALY measurement, is unlikely to change in a patient being treated for a chronic or recurrent condition.[991] Thirdly, QALYs measure only treatment outcome and not the process of health care. However, proponents of CAM emphasise that the process of health care also contributes to a patient's quality of life.[992] QALYs ignore the health care process in the quality of life assessment.

Thus the currently used generic QALY assessment of a CAM modality may not produce relevant estimates of the health benefits to the patient because it is insensitive to the values of patients, to patients' subjective judgment.

PCTs aiming to avoid litigation by patients will try to demonstrate that they have properly considered all the relevant factors in their exceptionality assessment.[993]

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[989] J Stone, *An Ethical Framework for Complementary and Alternative Therapists* (1st edn, Routledge 2002) 15.

[990] QALYs measure not only the amount of extra life that a treatment generates but also its quality, see eg E Jackson, *Medical Law: Text, Cases, and Materials* (2nd edn, OUP 2009) 43; see also chapter 1, Efficiency as Cost-Effectiveness.

[991] cf a patient treated successfully with orthodox treatment for an acute condition will most likely have a greater life expectancy after treatment; cf the QALY calculation of a cancer drug where the increased life expectancy is only a few months tends to militate against a NICE approval of the novel cancer drugs on the ground of lack of cost effectiveness. This is why the nominal threshold of £30,000 per QALY was raised in 2009 where the drug was expected to increase the life expectancy of a patient by more than three months; see A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 3.

[992] R Meenan, 'Developing Appropriate Measures of the Benefits of Complementary and Alternative Medicine' (2001) 6 J Health Serv Res Policy 38, 39–40 arguing that utility or quality of life may arise not only from health outcomes but also from their process of generation. Process characteristics, which are not identified in current assessments of quality of life or QALY evaluation, include increased patient autonomy, closer health practitioner-client relationship, longer consultation time and clearer explanations to the patient which may offset reduced physical function, producing greater overall utility. Process, however, does not necessarily influence health. Utility and health are distinct concepts, but this is to some extent also dependent on the definition of disease and illness, where disease is recognised by the healthcare system, and illness experienced by the patient. The patient's concept of illness allows the process of care to alleviate it without direct effects on the disease.

[993] Lawyers are becoming involved in the initial decision-making stage of public authorities in order to recognise problems early on, see eg L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' [2010] J Public Adm Res Theory (suppl 2) i243, i252.

They must be able to explain coherently why they have arrived at their decision in order to reduce the threat of judicial review. Avoiding litigation and its collateral costs may be unsettling for PCTs in light of the rather ambiguous criteria developed by the courts for judging exceptionality. PCTs may prefer to approve a large percentage of individual funding requests to avoid being challenged in the courts.[994] Threatened or actual judicial review challenges may, however, exert much more far reaching influences and lead to PCTs arriving at new policies and budgeting priorities.

4.5. The destabilising effect of judicial review challenges

As has been suggested above, the threat of judicial review may have a destabilising impact on a health authority's efforts to resolve the tension between individual demands and the needs of the local population in a consistent, fair and equitable manner. From the point of view of the health authority, judicial review litigation turning on the definition of ambiguous exceptionality criteria involves considerable expenditure in terms of finances and staff time devoted to the case.[995] The threat of judicial review may therefore encourage authorities to do what they can to avoid the risk of litigation.[996]

While a judicial review challenge where the case does not reach judgment carries no legal weight, the adjudication of judicial review litigation is likely to have a greater

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[994] J Maybin and R Klein, *Thinking about Rationing* (King's Fund, London 2012) 25 citing M Richards, 'Improving Access to Medicines for NHS Patients' (Department of Health 2008) stating that in 2007 almost two-thirds of IFRs for cancer treatments and three-quarters of IFRs for non-cancer treatments were granted approval, although the rate of approval varied in PCTs, with some approving all IFRs and one PCT approving none; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 25. In Mr Condliff's case, for example, a further IFR application for bariatric surgery, involving a cost of approximately £5,000, a relatively small sum compared with the cost of further litigation, was agreed by the PCT on the basis of new clinical information he provided meeting the criteria for exceptionality, see ibid 19.

[995] M Richards, 'Improving Access to Medicines for NHS Patients' (Department of Health, 2008) 63 referring to PCTs in 2007 receiving between one and 1017 funding requests per year, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089952.pdf on accessed 30 September 2012; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 9 citing National Prescribing Committee, 'A Comprehensive Survey of PCTs to Evaluate Local Decision Making Processes for Funding New Medicines' mentioning some PCTs receiving up to 1000 exceptional funding request per year.

[996] See n 994 above.

impact on health authorities. A judgment provides an authoritative decision in a particular case, has a significant impact on the parties involved and creates legal precedent. Thus, in the context of judicial review challenges of local authority decisions by individual claimants, Platt and others found that local authorities were often willing to reconsider their decisions and settle challenges early on in the judicial review process rather than having to respond to the outcome of the litigation.[997] However, as has been argued, judicial pronouncements on exceptionality criteria in judicial review proceedings may not provide clarity and are often ambiguous. Authorities investing resources responding to the perceived interpretation in one decision may find that other interpretations or decisions lead to a different conclusion.[998] In addition, responding to a judgment may be costly and unsettling and entail revisiting policies or budgeting priorities that have been carefully arrived at.[999] Even if there is no ambiguity, judgments are in the public domain and may encourage more potential claims by individual patients wanting to access low-priority treatments.

The destabilising effects of judicial review litigation, however, may have even more far reaching effects, effects beyond the immediate parties to the case, health authorities generally and potential future individual litigants. Thus according to Sabel and Simon, public law litigation destabilises the status quo generally, leads to public engagement, deliberation and negotiation, with consequences not only for the defendant institution but also for other institutions and practices. [1000] The need for transparency by the health authority, the need to account for its rationing decisions in public and the media involvement in such cases opens the system to broader

[997] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' [2010] J Public Adm Res Theory (suppl 2) i243, i252.
[998] See also ibid i251; see also A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 26–27 suggesting that there can be more than one lawful answer to a policy question.
[999] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' [2010] J Public Adm Res Theory (suppl 2) i243, i251.
[1000] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016 making this point in the context of the US with the less limited role of the judiciary ensuring that public authorities comply with obligations imposed by the US Constitution.

interests and voices.[1001] For Sheldrick judicial review litigation is a vehicle by which individuals and groups can bring pressure to bear on state institutions .[1002] The 'institutional leverage' provided by the courts may help 'in securing rights to participate in decision making or altering/expanding the parameters governing the implementation of a policy'.[1003]

From this standpoint it is then feasible to consider government policies on personalised healthcare and patient choice as a result and not simply the cause of the destabilisation of meso-level litigation and adjudication. The destabilisation may lead to an opening of the healthcare system to a new 'medical pluralism' to extend the provision of CAM in the NHS, already foreshadowed by the personal health budget pilots empowering patients to make choices regarding their treatment.[1004] However, this softening approach towards CAM needs to be seen at the same time in the light of the 'responsibilisation' of the patient and the escalating costs of healthcare.[1005]

4.6. Conclusion

The chapter has demonstrated that the exceptionality factors which have emerged from judicial review case law of IFR refusals are often ambiguous and may be of little assistance to the patient who has been refused CAM, absent illegality, procedural impropriety and unreasonableness, even with the greater intensity of scrutiny of the decision by the courts. As judicial review does not generally concern itself with the substance of the decision, as long as the PCT has explained the reasons for refusing the treatment, has taken into account all the relevant factors and

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[1001] A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 14 fn 56 citing B Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom' [2003] Journal of Comparative Policy Analysis 149.

[1002] B Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom' [2003] Journal of Comparative Policy Analysis 149, 155–56 providing the example of *R v North Derbyshire Health Authority, ex p Fisher* (1997) 8 Med LR 327 as possibly having played a role in the change of the PTC's policy concerning the use of Beta-interferon treatment.

[1003] ibid 156.

[1004] See chapter 1 discussing personal health budgets for use by patients with long-term chronic conditions , ie those conditions that are not amenable to a cure by biomedicine.

[1005] See chapter 1.

given appropriate weight to these factors – the requirements of the reasonableness framework of decision-making –, the patient is unlikely to be successful in an application for judicial review. If the PCT can demonstrate that it has considered the effectiveness of the CAM modality and also its cost-effectiveness, it is unlikely that the court will invalidate its decision.

However, as has been demonstrated, from the point of view of the health authority, judicial review proceedings involve considerable expenditure in terms of finances and staff time devoted to the case. In the view of the difficulty of interpreting the often ambiguous exceptionality criteria which have emerged from judicial review cases, PCTs may therefore concede an individual funding request that does not involve major treatment costs simply to avoid the expense of court proceedings and the possibility of a negative outcome for the PCT and the risk of setting a precedent that encourages yet more potential claims. This may in turn encourage patients to claim exceptional circumstances to obtain funding for CAM.

Public law litigation, apart from being costly and time-consuming for a health authority and setting new precedents, has, however, wider ramifications extending beyond the parties involved. The need for transparency by the health authority and the media interest in judicial review litigation opens the system to broader interests and voices and can be a means to bring pressure on public institutions.[1006] Public law litigation destabilises, leads to public engagement, deliberation and negotiation, and may lead to a restructuring of practices and of defendants' and other institutions in the long term.[1007] It can be seen as an incentive to change and as expanding the parameters governing the implementation of policies.[1008] In view of macro-level patient choice policies and the personalisation of healthcare policy public law litigation may therefore open up a greater space for CAM in NHS provision, already

[1006] B Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom' (2003) Journal of Comparative Policy Analysis 149, 155–56.
[1007] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016,1017.
[1008] B Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom' [2003] Journal of Comparative Policy Analysis 149, 156.

foreshadowed by the personal health budget pilots for patients with complex, long-term chronic conditions.

Patient choice of CAM funded by the NHS may receive further impetus from another direction. In the EU, patients have access to cross-border healthcare funded by their 'home' Member State. A new EU Directive on the application of patients' rights in cross-border healthcare, initiated by the national governments in 2002 and brought to fruition by the Commission (DG SANCO) in 2011[1009] will be transposed into national law by October 2013. The patient cross-border rights in the EU and the relevance for a treatment choice of CAM will be discussed in the next chapter.

[1009] W Palm and I A Glinos, 'Enabling Patient Mobility in the EU; Between Free Movement and Coordination' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 521–26.

Chapter 5
The destabilising effect of EU healthcare law: patient choice of CAM across borders

5.1. Introduction

The right of patients to receive healthcare in another EU Member State (host state), and to be reimbursed by the healthcare system of their 'home' Member State (home state), has been established in a series of judgments of the European Court of Justice (ECJ). This is despite the fact that the EU has no formal competence to regulate national healthcare.[1010] Cross-border healthcare was interpreted by the Court as being an economic service,[1011] within the meaning of the Treaty, which also applied to national healthcare systems. Prior authorisation in case of hospital care had to be based on objective, non-discriminatory criteria.[1012] For non-hospital care, prior authorisation was found to constitute a barrier to the freedom to provide services.[1013]

The chapter demonstrates that despite the paucity of cases which have been referred to the ECJ, the litigation of patients claiming rights to reimbursement from their own healthcare systems for healthcare services obtained in another EU Member State had the effect of destabilising the national healthcare systems, with effects far beyond the number of patients who used these rights.[1014] Litigation created legal uncertainty due to the risk of patients obtaining treatment, including CAM treatment, abroad to

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[1010] Article 152(5) EC provides that Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of healthcare services. This principle was affirmed by the ECJ in a number of cases, see eg Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931, para 17; Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 44; Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 146.
[1011] Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931, para 17.
[1012] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 85.
[1013] ibid, para 44.
[1014] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220, 222.

which they were not entitled in their home state, uncertainty as to the levels of reimbursement that should apply and when patients' home state could lawfully refuse prior authorisation.[1015]

These cases set in motion a restabilisation process which prompted political activity by the UK government and the NHS, from lobbying to a 'creative' adaptation of national healthcare policy.[1016] It led to the adoption of the EU Directive on cross-border healthcare, or the Patient Mobility Directive,[1017] expected to end the legal uncertainty about the care patients can receive abroad while allowing the NHS to maintain control over patients' entitlements,[1018] thus setting limits on the potential of expanding patient choice further within the EU. The chapter suggests that although the Directive forms part of a cycle of restabilisation in the EU it is unlikely to end legal uncertainty. It is argued that rather than ending legal uncertainty, the Directive perpetuates some of the issues that have caused the destabilising effects of ECJ case law on the English NHS and threatens potential legal challenge by patients claiming reimbursement for cross-border treatment. Thus, possible uncertainties regarding prior authorisation of cross-border treatment, the level of reimbursement and the undefined health benefit basket of the NHS remain. The scope for patients' claims for reimbursement from their health authorities[1019] causes further instability and may possibly expand the availability of CAM within the NHS.

[1015] NHS European Office, 'Patient choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

[1016] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220, 223; R Baeten and others, *The Europeanisation of National Health Care Systems: Creative Adaptation in the Shadow of Patient Mobility Case Law* (European Social Observatory 2010).

[1017] EU 2011/24/EU (Directive on the Application of Patients' Rights in Cross-Border Healthcare or 'Patient Mobility Directive') was adopted at EU level in March 2011 and is to be transposed into national law by October 2013.

[1018] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

[1019] At present, these claims will be assessed by PCTs and from April 2012 by CCGs, see Health and Social Care Act 2012.

The chapter first explains the legal framework underlying patient mobility in the EU. This is followed by the analysis of two CAM cases decided by the European Court of Justice, highlighting the greater emphasis placed on the economic nature of healthcare services than on scientific credentials, and the analysis of the case of *Watts*[1020] showing the applicability of ECJ case law to the NHS. The chapter then proceeds to discuss the destabilising effects of the ECJ's patient mobility case law generally and the likely impact of the new Patient Mobility Directive on the NHS patient claiming cross-border healthcare rights to CAM.

5.2. The legal framework

Prior to the decisions of the European Court of Justice in *Decker*[1021] and *Kohll*[1022] in 1998, patients were able to access treatment in another EU Member State under the social security legislation, the Regulation on the coordination of social security schemes, which is intended to cover people who either study or work abroad or require necessary medical treatment as tourists.[1023] It entitles the patient to the same benefits as the patients of the host state. In addition, the Regulation enables planned treatment abroad, as long as the patient has received prior authorisation from the competent institution in her home state.[1024] Such authorisation cannot be refused where the treatment is covered in the healthcare benefit basket of the home state and cannot be given without undue delay.[1025]

The activist approach to the interpretation of the social security legislation by the ECJ led to the EU Member States amending the social security legislation on several

[1020] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325.
[1021] Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés* [1998] ECR I-1831.
[1022] Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931.
[1023] Regulation 883/2004/EC, formerly Regulation 1408/71/EEC with its objective of coordinating the social security benefits provided by EU Member States.
[1024] Article 20(1) of Regulation 883/2004/EC.
[1025] Article 20(2) of Regulation 883/2004/EC provides that authorisation must be accorded 'where the treatment in question is among the benefits provided for by the legislation of the Member State where the person concerned resides and where he cannot be given such treatment within a time-limit which is medically justifiable, taking into account his current state of health and the probable course of his illness'.

occasions[1026] in order to restrict the effect of the ECJ's pronouncements.[1027] Since 1998, the Regulation on the coordination of social security schemes has been interpreted by the Court in the light of the freedom of movement provisions of the Treaty, which is beyond easy amendment by the Member States.[1028] The relevant Article of the Treaty[1029] provides that restrictions on the freedom to provide[1030] services[1031] within the Community shall be prohibited in respect of nationals of Member States.[1032] Consequently, patients now seek to use the free movement rights under the Treaty provisions as a means of accessing cross-border healthcare and then claim reimbursement of the cost of treatment from their home state, or seek to combine their claims under the Treaty provisions and the social security legislation.[1033]

[1026] The original Article 22 of Regulation 1408/71/EEC provided that authorisation may not be refused 'where the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he resides'. After the *Pierik* decisions in Case 117/77 *Bestuur van het Algemeen Ziekenfonds Dreuthe-Platteland v Pierik (No 1)* [1978] ECR 825 and Case 182/78 *Bestuur van het Algemeen Ziekenfonds Dreuthe-Platteland v Pierik (No 2)* [1979] ECR 1977, Article 22 was altered to provide that authorisation may not be refused 'where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease'.

[1027] V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 125.

[1028] ibid.

[1029] Article 56 TFEU.

[1030] The freedom to provide services includes the freedom to receive services, see Joined Cases 286/82 and 26/83 *Luisi and Carbone v Ministero de Tesoro* [1984] ECR 377, para 16.

[1031] Medical treatment constitutes services according to Article 57 TFEU (ex-Article 50 EC) see Case C-159/90 *The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan* [1991] ECR I-4685, para 16; Case C-158/96 *Raymond Kohll v. Union de caisses de maladie* [1998] ECR I-1931, para 17.

[1032] See generally AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003) 235 and V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 127.

[1033] eg Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325 concerning an English patient; see also J McHale, 'Commentary. Rights to Medical Treatment in EU Law. *R (Watts) v Bedford Primary Care Trust and Another*' (2007) 15 Med L Rev 99, 100.

5.3. CAM and the interpretation of the Treaty provisions

Despite the relatively small number of patient mobility cases that have been referred to the Court, the results of these cases have raised concerns within the Member States about the impact on the solidarity base of their healthcare systems and the deleterious effect on resource allocation decisions.[1034] A surprising outcome of these cases is the finding that cross-border access to healthcare includes a right to access not only orthodox medicine but also complementary alternative medicine (CAM), which is generally not publicly funded, or only to a very limited extent, in many EU Member States.[1035] A total of four cases referred to the ECJ to date have concerned CAM[1036] and two of these cases are discussed in more detail. The cases of *Geraets-*

[1034] K Veitch, 'Juridification, Medicalisation, and the Impact of EU law: Patient Mobility and the Allocation of Scarce NHS Resources' (2012) Med L Rev 362; C Newdick, 'The European Court of Justice, Trans-National Healthcare, and Social Citizenship – Accidental Death of a Concept' (2009) Wisconsin Intl L J 844.

[1035] eg Health Systems in Transition, *Italy* (European Observatory on Health Systems and Policies, Brussels 2009) 147; Health Systems in Transition, *France* (European Observatory on Health Systems and Policies, Brussels 2010) 219; Health Systems in Transition, *The Netherlands* (European Observatory on Health Systems and Policies, Brussels 2010) 166; Health Systems in Transition, *Belgium* (European Observatory on Health Systems and Policies, Brussels 2010) 198; cf Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit* [2004] ECR I-2641, which concerned climotherapy and balneotherapy, recognised as an appropriate and effective treatment by the patient's home state. Authorisation for reimbursement of the associated expenditure of the spa treatment was refused, because under the applicable German legislation it had not been established that it was absolutely necessary that the cure be provided outside Germany on account of the greatly increased prospects of success. The ECJ decided that Member States were precluded by the Treaty provisions on the freedom of movement from subjecting the reimbursement of such expenditure to conditions which were different from those applicable to cures taken in the patient's home state. These conditions had the effect of inhibiting cross-border receipt of healthcare services.

[1036] Case 117/77 *Bestuur van het Algemeen Ziekenfonds Dreuthe-Platteland v Pierik* (No 1) [1978] ECR 825 and Case 182/78 *Bestuur van het Algemeen Ziekenfonds Dreuthe-Platteland v Pierik* (No 2) [1979] ECR 1977 were not decided under the freedom of movement provisions but under a previous version of the Social Security Regulation changed in 1981, in the wake of the ECJ's *Pierik* decisions. The Dutch patient claimed reimbursement for hydrotherapy treatment obtained in Germany, a treatment which was considered of little value and inappropriate in Holland but was not specifically excluded from the benefits basket. The treatment had, however, shown considerable effectiveness in the patient's case. In *Pierik* (No 1), paras 15–18 the ECJ held that 'appropriate treatment' included treatment calculated to be effective for the condition from which the person suffers wherever it was provided and that authorisation for treatment may not be refused where the treatment in the Member State of residence is less effective than that which is available in another Member State. In *Pierik* (No 2) a further question was referred to the Court, namely whether authorisation of treatment could be refused where the treatment for medical reasons was not considered as falling within the field of health treatment or was not considered of any value. The Court stated, at paras 10–13, that it is for the institution objectively to assess the medical grounds for refusing

Smits[1037] and *Inizan*[1038] help to underline that the questions of the lack of availability and lack of recognition of CAM as effective treatment in the patient's home state were given short shrift by the Luxembourg Court.

5.3.1 The case of *Geraets-Smits*

Geraets-Smits[1039] involved a Dutch national who suffered from Parkinson's disease. She was admitted to a German hospital for several weeks where she obtained multi-disciplinary treatment consisting of medication together with physiotherapy, ergotherapy and socio-psychological care.[1040] The Dutch sickness insurance institution refused to reimburse the costs incurred by the patient because, firstly, adequate treatment for Parkinson's disease was available in the Netherlands[1041] and, secondly, the specific clinical treatment provided in Germany was not regarded as normal treatment within the professional circles concerned.[1042] Rather than the sickness insurance system being based on a pre-established list of types of treatment,[1043] the Netherlands legislature had enacted a rule that the test for a

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authorisation, having regard to the effectiveness of the treatment in question, but where the institution acknowledges that the treatment constitutes an effective treatment then it cannot refuse authorisation. Thus patients would be able to obtain authorisation for treatment which was not included or even deliberately excluded from the healthcare package of their Member State of residence; see generally AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003) 255 arguing that the judgment comes close to the recognising the free movement of patients under the social coordination legislation.

[1037] Case C-157/99 B.S.M. *Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473.

[1038] Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403.

[1039] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473 combined the reference of two cases to the ECJ but, while *Peerbooms* involved intensive care therapy of a patient in a coma, only *Geraets-Smits* involved treatment falling in the category of CAM.

[1040] Opinion of Mr Advocate General Ruiz-Jarabo Colomer, ibid, para 3.

[1041] The expert neurologist appointed by the national court also concluded that there was no clinical or scientific evidence that the specific approach used in Germany was more appropriate, see ibid, para30.

[1042] ibid, para 29; Article 3 Verstrekkingenbesluit Ziekenfondsverzedering 1966 (Holland).

[1043] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 63.

treatment to be regarded as a qualifying benefit[1044] was that it had to be considered 'normal within the medical professional circles concerned'.[1045] This is not unusual in that many Member States leave it up to healthcare professionals to define the insurance package according to open criteria such as 'adequate and appropriate' treatment or treatment 'normal in the professional circles concerned' rather than establish fixed treatment lists which would require frequent updating due to rapidly changing developments in medicine.[1046]

Whilst the European Court of Justice in principle accepts such open criteria,[1047] it considered the Dutch national requirement for the treatment to be regarded as 'normal within the professional circles concerned', to constitute an obstacle to the freedom to provide services.[1048] In essence, the argument of the Dutch sickness insurance funds meant that treatments would only be recognised as health benefits if they are considered normal within Dutch medical circles.[1049] Although foreign expertise through contributions to medical science made by specialists from other states at international conferences and in specialist literature would have an impact on Dutch medical circles,[1050] the fact that it was up to the sickness insurance funds in the Netherlands to decide what was normal, and therefore a benefit under its social security legislation, might lead to non-recognition of new, revolutionary or

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[1044] ibid, para 91; Article 3 Verstrekkingenbesluit Ziekenfondsverzedering 1966 (Holland) and see Article 22 of Regulation 1408/71EC providing that authorisation for a treatment may not be refused where the treatment is a benefit provided for under the Member State's legislation.
[1045] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 23.
[1046] See AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003) 302.
[1047] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, paras 85 and 87.
[1048] ibid, para 67 and 90 although the ECJ also accepted that there could be overriding reasons to justify barriers to the freedom to provide services, paras 72–74.
[1049] A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 Eur L J 345, 355.
[1050] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 93 referring to the argument advanced by the Netherlands government.

experimental treatments regarded as normal in other EU Member States.[1051] The ECJ held that determination of what is normal required reference to international medical science and standards, as without such reference, national scientific views would prevail over international opinions, leading to treatment habitually carried out on national territory always being preferred in practice.[1052] Therefore where a treatment is 'sufficiently tried and tested according to international medical science' it should be regarded as 'normal' and recognised as a benefit under the sickness insurance scheme.[1053]

In order to assess what criteria satisfy treatments that are 'sufficiently tried and tested according to international medical science', the national institution must take into account all relevant information including 'existing scientific literature and studies, the authorised opinions of specialists and the fact that the proposed treatment is covered or not covered by the sickness insurance system of the Member State in which the treatment is provided'.[1054] With regard to the latter consideration, Koutrakos' point is interesting to note, namely that the Member State's assessment of what should be covered in its own sickness insurance system is irrelevant whereas, according to the principle of free movement, it matters whether the treatment is covered in the Member State where treatment is provided.[1055] The Court also did not clarify how the Member State should determine the relevant 'international medical science' considering the constant developments in the

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[1051] A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 Eur L J 345, 356.
[1052] Case C-157/99 *B.S.M.Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 96; A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 Eur L J 345, 356.
[1053] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, paras 94 and 108. And see A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 Eur L J 345, 356.
[1054] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 98; see also P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673, 684 pointing out that the Court did not provide any indication as to the weight to be attached to each of these criteria.
[1055] P Koutrakos, 'Healthcare as an Economic Service under EC Law' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Hart 2005) 118.

understanding of disease and treatment, the educational and cultural differences between healthcare professionals in the EU, and even more so healthcare professionals outside the EU.[1056] Van der Mei, for example, asks whether there is such a thing as an international standard in medical circles.[1057] Medical scientists may not always recognise the progress made by scientists in other Member States[1058] nor agree on the adequacy or appropriateness of treatments provided in other Member States.[1059] Are ergotherapy and socio-psychology recognised as effective, tried and tested treatments for Parkinson's Disease in the EU generally? Is it sufficient that the treatment is available in any Member State and covered by its healthcare system? What if the healthcare cover of that Member State changes? As van der Mei points out, the Court did not interpret 'international standards'.[1060] Rather, what the Court focused on was whether the Dutch rules were a barrier to the freedom to provide services and protected national healthcare providers.

5.3.2 The case of *Inizan*

Divergent views by healthcare professionals on the appropriateness of the treatment were also apparent in the case of *Inizan*.[1061] The patient in the case had undergone pain relief and psychological treatment for her acute back pain at specialist centres in France where she was insured, but the treatment had proved unsuccessful. She applied for authorisation from her sickness insurance fund to undergo integrative medicine and natural therapy at a German hospital which was equipped with a natural therapy and integrative medicine unit.[1062] Authorisation for the treatment,

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[1056] TK Hervey and L Trubek, 'Freedom to Provide Healthcare Services within the EU: An Opportunity for a Transformative Directive', Law in New Governance Law Taskforce II Conference Paper, UCL London, May 2006, 9.
[1057] AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003) 303.
[1058] ibid.
[1059] TK Hervey and JV McHale, *Health Law and the European Union (*CUP 2004) 137 arguing that especially regarding new treatment there is likely to be a difference of professional opinion.
[1060] AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003) 303.
[1061] Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403.
[1062] Facts stated in Opinion of Advocate General Ruiz-Jarabo Colomer, ibid 12406.

which under French law would be given only if the same or equally effective treatment could not be obtained in France without undue delay,[1063] was refused.

The national court referred questions on the compatibility of the Regulation on the coordination of social security schemes[1064] with the freedom of movement provisions of the Treaty,[1065] and on the lawfulness of the refusal of authorisation by the sickness insurance fund to the European Court of Justice. One of the points raised by the defendant sickness insurance fund was that treatment of pain by means of natural therapy and integrative medicine was not scientifically recognised, and was therefore not a benefit available under the French social security system.[1066] The French government added that, although the German treatments were not practised in France under the same name and in the same form, it was possible to keep the condition under control by using the range of different treatments available in France. The fundamental difference was that the treatments were not available at one centre, unlike in Germany,[1067] but they were available without undue delay, therefore justifying refusal of authorisation under the Regulation on the coordination of social security schemes. The patient contended that she had already undergone these treatments in the past without success, and that, in accordance with the principle of freedom to receive services, she was entitled to move freely to another Member State to receive treatment not available under the French healthcare system and be reimbursed for the cost of that treatment.[1068] She also adduced evidence that the treatment sought in Germany was covered by the public sickness insurance scheme in Germany.[1069]

[1063] Social Security Code (France), L.332-3, L.766-1 and R.332-2 providing for similar conditions as Article 22 of Regulation 1408/71/EEC and see V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 133.
[1064] Article 22 of Regulation 1408/71/EEC.
[1065] Ex-Article 49 EC, now Article 56 TFEU.
[1066] Opinion of Advocate General Ruiz-Jarabo Colomer in Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403, 12411, para 17.
[1067] ibid 12413, para 19.
[1068] ibid 12411, para 16.
[1069] ibid 12407, para 8.

As Montgomery points out, the case was a dispute about the effectiveness of complementary alternative therapy.[1070] However, neither the question of the effectiveness of the treatment nor its scientific rationale was mentioned by the ECJ. Rather, the Court viewed the case as concerning authorisation procedures for hospital care under the Regulation on the coordination of social security schemes and the Treaty provisions on freedom of movement,[1071] and decided that the prior authorisation was compatible with the Treaty provisions.[1072] Despite the protestation by the sickness insurance funds that the treatment sought in Germany was not scientifically recognised and therefore not covered by the insurance,[1073] the Court found that the treatment was 'among the benefits provided for by the legislation of the Member State on whose territory the insured person resides'[1074] and that 'the same or equally effective treatment' could not be given without undue delay in that Member State.[1075] As a consequence, by supporting the patient's case[1076] the ECJ required[1077] treatment considered inappropriate by the medical healthcare professionals in the patient's home state to be funded by its insurance system.[1078] Moreover, the concept of 'the same or equally effective treatment' is likely to be

[1070] J Montgomery, 'The Impact of European Union Law on English Healthcare Law' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Hart 2005) 153.
[1071] Case C-56/01 *Patrizia Inizan v. Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403, para 39.
[1072] ibid, para 60.
[1073] Opinion of Advocate General Ruiz-Jarabo Colomer in ibid 12406, para 17.
[1074] ibid 12403, para 42.
[1075] ibid 12403, paras 37 and 45.
[1076] ibid, para 60 where the Court stated that although the freedom of movement provision did not preclude prior authorisation, such authorisation was subject to the condition that the patient could not receive treatment appropriate to his illness in his Member State of insurance (home state), but that authorisation can be refused where treatment which is the same or equally effective can be obtained without undue delay in the patient's Member State of insurance, and see P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673, 679–80.
[1077] Reminiscent of the decision in Case 117/77 *Bestuur van het Algemeen Ziekenfonds Dreuthe-Platteland v Pierik (No 1)* [1978] ECR 825, 830.
[1078] J Montgomery, 'The Impact of European Union Law on English Healthcare Law' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Hart 2005) 153 pointing out that the decision subordinates professional control of which treatments are effective (and also which are covered by the health system) to the freedom of movement and the market in services.

subject to disagreement and might encourage further litigation,[1079] and this may be especially so in the context of unproven complementary alternative medicine.

5.4. The English patient's access to cross-border healthcare

The ECJ, with its wide interpretation of the definition of healthcare benefits, therefore brought non-orthodox CAM treatment within the reach of the EU patient who would otherwise not have been able to obtain it free of charge in her home state. Both these cases, however, did not concern a national healthcare system based on taxation but rather reimbursement[1080] or benefits-in-kind[1081] systems which were insurance based.[1082] Until the case of *Watts*,[1083] none of the cross-border patient mobility cases before the European Court of Justice had involved a national healthcare system based on taxation such as the English NHS.

5.4.1 The case of *Watts*

Although already foreshadowed in the case of *Müller-Fauré* and *van Riet*,[1084] *Watts* finally settled that the principles of free movement were applicable to the NHS and

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[1079] TK Hervey and JV McHale, *Health Law and the European Union (*CUP 2004) 137.

[1080] In a reimbursement system, the patient pays the healthcare provider for the treatment received and is later reimbursed by the sickness insurance fund for the costs incurred; P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673 fn 18; see eg Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931.

[1081] In a benefits-in-kind system based on insurance, patients can receive care from any contracted provider who in turn is paid directly by the sickness insurance institutions on the basis of agreed fees for services; P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673 fn 20; see eg Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473 concerning hospital-based services; Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509 concerning non-hospital-based services.

[1082] V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 117 and P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673, 675.

[1083] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325.

[1084] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509 where the ECJ appeared to reject the UK argument that the NHS did not provide services for remuneration, despite the fact, that the connection between medical services and the remuneration

that NHS patients were entitled to receive treatment in another EU Member State at the expense of the NHS. As the Court held:[1085]

> The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service … does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply …[1086] It must therefore be found that Article 49 EC applies … regardless of the way in which the national system with which [a] person is registered and from which reimbursement of the cost of those services is subsequently sought operates.[1087]

In 2003, Mrs Watts, a patient from Bedfordshire, had gone to France for hip replacement surgery to avoid the long waiting time for treatment under the NHS. She had been informed by her PCT that she would have to wait for about one year before the operation would be carried out in England. This waiting time was later reduced to a few months, as her condition had deteriorated, but she preferred to undergo the operation in France where it had been scheduled earlier. However, she had not obtained prior authorisation from her PCT as required under the Regulation on the coordination of social security schemes.[1088] Mrs Watts later sought reimbursement for the costs of treatment incurred abroad. Her application to the High Court for judicial review of the decision by the Secretary of State's refusal to cover these costs failed. On appeal, two of the key issues of EU law concerned the definition of 'undue delay' and the question of the grant or refusal of prior authorisation. The ECJ held that Mrs Watts had simultaneous rights to cross-border

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for these services is indirect; see also P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673, 677–78.

[1085] J McHale, 'Commentary. Rights to Medical Treatment in EU Law. *R (Watts) v Bedford Primary Care Trust and Another*' (2007) 15 Med L Rev 99, 104.

[1086] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 89.

[1087] ibid, para 90.

[1088] Article 22 of Regulation 1408/71/EEC, now Article 20 of Regulation 883/2004/EC; see text of Regulation n17.

healthcare under the freedom of movement provisions[1089] and the Regulation on the coordination of social security schemes.[1090] The criteria for assessing whether there is 'undue delay' under the former or whether a period of waiting is acceptable under the latter are the same. The waiting time must not exceed a period that is acceptable on the basis of an objective medical assessment of the patient's clinical needs.[1091] Nevertheless, the Court accepted that a system of prior authorisation of treatment abroad was compatible with the Treaty, but that the criteria for authorisation had to be available in advance, objective and non-discriminatory.[1092]

5.5. The destabilising effects of the ECJ's case law

While the rulings on the cases discussed cover different factual situations and different points of law, the decision in *Watts* specifically, and ECJ patient mobility case law generally, has created uncertainty for national healthcare systems. They do not only pose problems regarding the need to change existing healthcare policy and the implementation of new policies,[1093] but also regarding the risk of further legal challenge. New European rights have been created, such as the right to obtain elective, non-emergency hospital treatment in another EU Member State without

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[1089] Article 49 EC, now Article 56 TFEU.
[1090] Article 22 of Regulation 1408/71/EEC, now Article 20 of Regulation 883/2004/EC.
[1091] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, paras 79 and 119; J McHale, 'Commentary. Rights to Medical Treatment in EU Law. *R (Watts) v Bedford Primary Care Trust and Another*' (2007) 15 Med L Rev 99, 103-104; M Cousins, 'Patient Mobility and National Health Systems' (2007) 34 LIEI 183, 185.
[1092] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 116 and see discussion in J McHale, 'Commentary. Rights to Medical Treatment in EU Law. *R (Watts) v Bedford Primary Care Trust and Another*' (2007) 15 Med Law Rev 99, 104 and M Cousins, 'Patient Mobility and National Health Systems' (2007) 34 LIEI 183, 187.
[1093] See eg Department of Health, 'Patient Mobility. Advice to Local Healthcare Commissioners on Handling Requests for Hospital Care in other European Countries following the ECJ's judgment in the Watts case, London, 16 April 2007' <www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073850> accessed 23 August 2012; R Baeten and others, *The Europeanisation of National Health Care Systems: Creative Adaptation in the Shadow of Patient Mobility Case Law* (European Social Observatory 2010) 21.

prior authorisation.[1094] To change financial and administrative policies and procedures so that they do not violate EU internal market law is not an easy undertaking. As Greer and Rauscher point out, an unstable legal environment is not desirable for running a bureaucracy.[1095] It is not an attractive option, even if just a few people choose to challenge a policy and the impact of cross-border mobility is expected to be minor.[1096] The existence of legal uncertainties was acknowledged by the NHS European Office in its report on the implications of the EU Directive on cross-border healthcare.[1097] These uncertainties also pertain to the patient accessing CAM across borders, and regard issues such as prior authorisation and the distinction between hospital and non-hospital care, the level of reimbursement and the calculation of costs for a national health system without tariffs, and the problem of an undefined healthcare benefit basket.

5.5.1 CAM and the issue of prior authorisation for hospital versus non-hospital treatment

The dual routes of cross-border patient mobility under the Treaty provisions and the Regulation on the coordination of social security schemes developed in the case law of the ECJ distinguish between the need for prior authorisation for hospital and non-

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[1094] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220, 222.

[1095] ibid.

[1096] W Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' (2008) <http://ssrn.com/abstract=1277110> accessed 5 May 2012, 36 stating that the overall financial impact of patient mobility is small, with cross-border healthcare accounting for 1% of public expenditure on healthcare in 2006/2007 valued at about 9.7 billion Euros; Department of Health, 'Cross Border Healthcare and Patient Mobility: Data and Evidence Gathering, York Health Economics Consortium, August 2010' (the 'York Study') <www.networks.nhs.uk/nhs-networks/cross-border-healthcare-network/documents/York>, accessed 5 May 2012, referred to 750 people travelling to Europe in 2009 under the social coordination route (York Study 16). Just thirty people applied for authorisation of treatment on the Continent under the Article 56 TFEU route, which was refused in all but six cases (York Study 58) cf ibid 19 referring to the suspicion by the Department of Work and Pensions (DWP) that many of the 40,000 claims under the European Health Insurance Card for necessary treatment were health tourism claims rather than for genuine emergencies.

[1097] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 2 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

hospital treatment or extramural and intramural care. Much of the ECJ case law turns on the restrictive policies applied by Member States refusing patients authorisation to obtain healthcare outside their home state.

Although the Regulation on the coordination of social security schemes[1098] lays down a prior authorisation scheme for treatment sought in another EU Member State, the ECJ had already held, in *Kohll*, that a prior authorisation requirement is incompatible with the freedom of movement provisions of the Treaty in the case of *non-hospital* treatment.[1099] The orthodontic treatment obtained in Germany by Mr Kohll, a Luxembourg resident, was a type of service that, despite being of a special nature, was considered to be within the ambit of the fundamental principle of freedom of movement.[1100] An authorisation scheme for treatment was only held to be justified where it served the objective of maintaining a balanced medical and hospital service open to all[1101] or was necessary to ensure the financial balance of the social security regime.[1102]

The judgment in *Kohll*, involving the Luxembourg healthcare system which was based on reimbursement, was confirmed and extended by the ECJ in relation to the benefits in kind system of the Netherlands in the *Müller-Fauré* case[1103] concerning a Dutch national who had received dental treatment in Germany without prior authorisation. The ECJ held that the removal of the requirement of prior authorisation in respect of non-hospital services was unlikely to seriously undermine the financial balance of a healthcare system,[1104] although the removal of such a

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[1098] Article 20 of Regulation 883/2004/EC, ex-Article 22 of Regulation 1408/71/EEC.
[1099] Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931, para 35.
[1100] ibid, para 20.
[1101] ibid, para 50.
[1102] ibid, para 41.
[1103] Case C-385/99 V.G. *Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; see generally W Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' (2008) 18 <http://ssrn.com/abstract=1277110> accessed 5 May 2012.
[1104] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 74.

requirement might cause financial imbalance in the case of hospital services.[1105] However, the Court conceded that it recognised the concerns of the Member States.[1106] The Court suggested that, while an individual case would not have a significant impact on the financing of a system, it was necessary to adopt an overall approach in assessing the consequences of the freedom to provide health-related services.[1107] For reimbursement to be lawfully refused for non-hospital treatment obtained abroad, the healthcare institution would have to argue more than that paying for one patient would lead to paying for all the other patients in a similar situation and that this would exceed its budget.[1108] The burden would be on the institution to show that the number of patients accessing cross-border healthcare is so large that the financial balance of the entire health system is put at risk.[1109] Thus, if a Member State were to submit evidence in future about the exodus of its patients for extramural cross-border care jeopardising its healthcare system, the prior authorisation requirement may be justified.[1110] Such evidence may not be easy to

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[1105] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 81; see also N Bernard, 'Between a Rock and a Soft Place: Internal Market versus Open Co-ordination in EU Social Welfare Law' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Hart 2005) 273 pointing out that the Court had already concluded in the earlier case of Case C-157/99 *B.S.M.Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, paras 76–80 that hospital services required more planning by the national authorities regarding the number of hospitals, their geographic distribution and the facilities and services which they provided.

[1106] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 74; AP van der Mei, 'Cross-Border Access to Medical Care: Non-Hospital Care and Waiting Lists' (2004) 31 Legal Issues of Economic Integration 57, 65–66; M Flear, 'Case C-385/99 *V.G. Mueller-Faure v Onderlinge Waarborgmaatschappij O.Z Zorgverzekeringen U.A. and E.E.M van Riet v Onderlinge Waarborgmaatschappij Z.A.O Zorgverzekeringen*, Judgment of the Court of 13 May 2003' (2004) 41 CMLE 209, 215–17.

[1107] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para74.

[1108] AP van der Mei, 'Cross-Border Access to Medical Care: Non-Hospital Care and Waiting Lists' (2004) 31 Legal Issues of Economic Integration 57, 66.

[1109] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 74; See also AP van der Mei, 'Cross-Border Access to Medical Care: Non-Hospital Care and Waiting Lists' (2004) 31 Legal Issues of Economic Integration 57, 66.

[1110] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509,

come by when data on cross-border care under the Treaty provisions is inaccurate,[1111] with the consequence that healthcare systems are left open to the possibility of a set of interest groups raising legal challenges as part of broader political strategies.[1112]

A wide interpretation of non-hospital services

In *Müller-Fauré*[1113] the Court also suggested that it may not always be easy to draw a distinction between intramural and extramural care. For example, there are services which are capable of being provided either in a hospital environment or by a healthcare practitioner in her surgery or in a health centre and, in the ECJ's view, such services should be placed on the same footing as non-hospital services.[1114] Van der Mei reasons, from the broad interpretation given to the meaning of extramural care, that it is unimportant where the treatment is actually provided, rather what matters is that the treatment is capable of being provided outside a hospital.[1115] Thus intramural care most likely only refers to treatment which *can* only be provided in hospital, and the mere fact that the treatment is provided in hospital or by a healthcare practitioner based in a hospital would not suffice to class it as hospital care.[1116] Complementary alternative treatments, often provided in English hospitals to cancer patients, to pregnant women during delivery, or in pain clinics, would most

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para 95; P Koutrakos, 'Healthcare as an Economic Service under EC Law' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Hart 2005) 127–28.

[1111] Department of Health, 'Cross Border Healthcare and Patient Mobility: Data and Evidence Gathering, York Health Economics Consortium, August 2010', 19 <http://www.networks.nhs.uk/nhs-networks/cross-border-healthcare-network/documents/York> accessed 5 May 2012.

[1112] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220, 222.

[1113] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 75.

[1114] ibid.

[1115] AP van der Mei, 'Cross-Border Access to Medical Care: Non-Hospital Care and Waiting Lists' (2004) 31 Legal Issues of Economic Integration 57, 65.

[1116] See also M Flear, 'Case C-385/99 *V.G. Mueller-Faure v. Onderlinge Waarborgmaatschappij O.Z Zorgverzekeringen U.A. and E.E.M van Riet v. Onderlinge Waarborgmaatschappij Z.A.O Zorgverzekeringen*, Judgment of the Court of 13 May 2003' (2004) 41 CMLE 209, 224 arguing that the concept of intramural care could be reduced to a minimum if all treatment that is capable of being provided on an extramural basis anywhere in the EU is classified as such.

likely be considered extramural care, as the administration of CAM generally does not require a hospital environment. The definition of what constitutes extramural care was not touched on by the ECJ in the case of hospital-based CAM in *Inizan*[1117] and in the case of CAM provided in a spa setting in *Leichtle*.[1118] CAM treatment provided within organised facilities, on the reasoning in *Müller-Fauré*, might well be considered extramural treatment and would not require prior authorisation.[1119] Since the distinction between the two types of care is, however, also decisive in determining the applicable reimbursement regime, precise criteria ought to be set to distinguish between them.[1120] As van der Mei predicts, future legal challenge is likely since doctors, hospital managers and policy-makers in the various Member States are likely to have different views as to which types of treatment require intra- or extramural care.[1121]

The argument of small numbers

In *Müller-Fauré* the Court contends that cross-border patient mobility for extramural care is limited for practical and psychological reasons. Practical barriers include linguistic differences, geographical distance, the cost of staying abroad and the lack of information about treatment facilities in other Member States.[1122] Psychological

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[1117] Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403, para 55 where the multidisciplinary CAM treatment provided to a patient with Parkinson's disease was given in hospital.

[1118] Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit* [2004] ECR I-2641; see also W Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' (2008) 22, at <http://ssrn.com/abstract=1277110> accessed 5 May 2012; cf Hatzopoulos who considers spa treatment to be assimilated with outpatient treatment although it is provided in organised facilities as no prior authorisation appears to be necessary in V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 134.

[1119] cf Case C-56/01 *Patrizia Inizan v. Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403, para 55 where the multidisciplinary CAM treatment provided to a patient with Parkinson's disease was given in hospital.

[1120] P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673, 686.

[1121] AP van der Mei, 'Cross-Border Access to Medical Care: Non-Hospital Care and Waiting Lists' (2004) 31 Legal Issues of Economic Integration 57, 65–66.

[1122] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 95 and see V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 139.

factors are related to the medical practitioner's proximity to the residence and the home environment of the patient, cultural affinities, and the relationship of trust with the treating doctor.[1123] As Koutrakos points out, the Court, by relying on its own assessment of what it views as objective factors, concluded that the requirement for prior authorisation in the case of non-hospital treatment is unjustified.[1124] According to him, patients benefit from the existence of these non-legal barriers which maintain the distinct healthcare markets in the EU.[1125] Patients therefore gain from the lack of integration of healthcare markets, without which they would not be able to obtain the reimbursement of unauthorised extramural cross-border healthcare. Ironically, if a considerable number of patients fled their own country to benefit from healthcare across the borders, the objective, non-legal barriers enumerated by the ECJ would no longer reflect reality accurately. Greater integration of the healthcare markets would then possibly justify national regulatory criteria restricting patients' access to extramural healthcare abroad,[1126] although the onus would be on the home state to prove that there was an exodus of patients to other Member States.[1127]

5.5.2 CAM and the issues of the level of reimbursement and the calculation of costs

Patients using the social coordination route under the Regulation on the coordination of social security schemes[1128] have the cost of their treatment covered as if they were insured in the state of treatment, the host state.[1129] Depending on the healthcare system of the host state, the patient does not have to make any advance payment, in

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[1123] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 95 and see V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 140.

[1124] P Koutrakos, 'Healthcare as an Economic Service under EC Law' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Hart 2005) 127.

[1125] ibid.

[1126] ibid 128.

[1127] See n 1109 and text to n 1109.

[1128] Article 20 of Regulation 883/2004/EC, ex-Article 22 of Regulation 1408/71/EEC.

[1129] Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403, paras 17 and21; Case C-368/98 *Abdon Vanbraekel and others v Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363, para 32; Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, paras 112 and 115.

contrast to the Treaty-based access route, which necessitates the patient applying for reimbursement of the cost of her treatment from her home state.[1130]

Reimbursement regimes

The level of reimbursement under the two routes varies. Under the Regulation on the coordination of social security schemes route, the patient will receive a refund of the costs according to the legislation of the Member State where treatment was provided.[1131] Where the treatment has been authorised, the costs of the patient's treatment are generally refunded direct by the home state to the host state. Where authorisation has been refused but the patient still travels abroad to obtain healthcare, the patient will have to pay all the costs upfront and takes a considerable financial risk.[1132] Since the rules as to reimbursement vary from one Member State to another, the patient who has been refused prior authorisation may face different upfront costs depending on the regulations in the host state.[1133] However, as the European Court of Justice decided in *Vanbraekel*,[1134] a patient may in such a case receive more money than he actually expended if the cost of treatment in the host state was lower than in her home state. Ms Descamp received not only reimbursement of the actual costs paid in France for her treatment, which was lower than the tariff for the same treatment in Belgium, her home state, but the additional amount corresponding to the difference between the tariffs in France and in Belgium.[1135] The reasoning of the ECJ for granting such a bonus to the patient was that this did not impose any additional burden on the home state, and the additional reimbursement did not have a significant effect on that state's social security

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[1130] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, paras 103 and 106. And see also comments in V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP. Oxford 2005) 143–44.
[1131] Article 35 of Regulation 883/2004/EC.
[1132] See discussion by A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 ELJ 345, 363.
[1133] M Cousins, 'Patient Mobility and National Health Systems' [2007] 34 LIEI 183, 193.
[1134] Case C-368/98 *Abdon Vanbraekel and others v Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363.
[1135] A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 ELJ 345, 362 describing a net gain for the patient of over 25% of the treatment costs amounting to FRF 11,326.45.

system.[1136] Not to guarantee an equally advantageous level of cover for the patient in another EU Member State would have the effect of making the provision of services between Member States more difficult, and would constitute an obstacle to the freedom to provide services.[1137]

In contrast to the Regulation on the coordination of social security schemes framework, under the Treaty provisions the patient always has to pay for her treatment in advance in the host state and will receive reimbursement at the tariff applicable in her home state.[1138] As the ECJ pointed out in *Müller-Fauré*,[1139] nothing prevents a Member State from fixing the amounts of reimbursement of foreign care, provided those amounts are based on objective, non-discriminatory and transparent criteria. This may of course lead to a patient only being reimbursed a fraction of the money he has expended in the host state.[1140] At the same time it would potentially leave the home state open to an influx of patients from other states benefiting from its low treatment costs. Thus, whilst the Regulation on the coordination of social security schemes route may enable the patient to profit from her treatment because of a favourable tariff in her home state, under the Treaty provision the patient may be financially penalised where he has paid more for the treatment than the refundable amount under the tariff of her home state.[1141] Hatzopoulos suggests that this conclusion is imposed by common sense, since a healthcare institution which has not authorised treatment abroad may not be compelled to pay more for treatment

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[1136] Case C-368/98 *Abdon Vanbraekel and others v Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363, para 52.
[1137] ibid, para 45.
[1138] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 95.
[1139] ibid, para 107.
[1140] See eg ibid, para 106 concluding that the patient would only receive 221.03 Euros instead of 3,806.35 Euros , the actual cost of treatment; see also A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 ELJ 345, 363 and P Koutrakos, 'Healthcare as an Economic Service under EC law' in M Dougan and E Spaventa (ed), *Social Welfare and EU Law* (Hart 2005) 127.
[1141] V Hatzopoulos, 'Killing National Health and Insurance Systems but Healing Patients?' (2002) 39 CMLRev 683, 702.

abroad than if the treatment had been delivered within its borders.[1142] Arguably, Hatzopoulos' reasoning is difficult to square with the fact that there is no need for prior authorisation in the case of non-hospital care. Of course, in the event that authorisation has been granted for non-hospital care the patient could choose which route will be more profitable. Where there has been no authorisation for non-hospital treatment, the patient will have to rely on the reimbursement at the tariff of her home state under the Treaty provisions. However, one of the problems for tax-based health systems such as the NHS is that there are no comparable tariffs for reimbursement, as the treatment is free to the patient.[1143] As a consequence, there is uncertainty as to the level of reimbursement a patient will be entitled to and the need to set up a system of tariffs and of reimbursement for healthcare services.[1144]

Calculation of cost

In the context of hospital treatment, the ECJ ruled in the case of *Watts* that treatment that was authorised or should have been authorised under the Treaty provisions must be reimbursed by the national health system based on objectively quantified costs of equivalent treatment.[1145] The need for quantification of treatment costs will also apply to claims for reimbursement of cross-border non-hospital care, whether such treatment will be orthodox medical treatment or CAM. Under the current system of public funding it may not always be possible to say what the cost of a particular treatment is.

As Davies argues, where the NHS attributes costs to a particular procedure or treatment, this may be challenged.[1146] In his view, in order for the NHS to avoid

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[1142] ibid, fn 101.
[1143] W Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' (2008) 26, <http://ssrn.com/abstract=1277110> accessed 5 May 2012.
[1144] See comments by V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G de Burca (ed), *EU Law and the Welfare State* (OUP 2005) 146.
[1145] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 143 where the Court added that such reimbursement would not have to cover more than the costs actually charged to the patient in the state of treatment (host state).
[1146] G Davies, 'The Effect of Mrs Watts Trip to France on the National Health Service' (2007) 18 KCLJ 158, 165.

writing blank cheques to patients claiming reimbursement of cross-border treatment, it is necessary to establish the costs of treatments objectively and transparently, and for these costs to be made publicly available.[1147] However, the prices which are set may be open to legal challenge since they involve controversial and difficult assessments. The costs of personnel, equipment and the costs of the infrastructure will have to be included; what about the costs of any additional consultations and tests, treatment of any side-effects or complications arising from the treatment of a patient's condition? As the NHS European Office stresses, defining the level of reimbursement is difficult when prices are set by PCT commissioners, or subject to negotiations between commissioners and providers and therefore subject to local variations. In addition, a tariff may also cover a package of care rather than a simple procedure, and may need to be 'unbundled' if the patient receives a different package of care abroad.[1148]

Apart from likely legal challenges, keeping costs artificially low may discourage English patients from seeking cross-border care under the Treaty provisions, and would therefore constitute a significant barrier to freedom of movement to EU Member States with higher medical treatment costs.[1149] Patients would not only have to pay the higher costs upfront but would also not be reimbursed the total cost of extramural treatment where the tariff in their home state was lower.[1150] However, although the English patient travelling abroad to receive extramural CAM treatment will have the same level of healthcare cover she would have had at home, she may

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[1147] ibid where Davies also points out that once each treatment has been attributed a price, NHS healthcare may start to resemble the insurance-based benefit-in-kind systems prevalent in some of the EU states or even resemble private healthcare systems.

[1148] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 4 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

[1149] M Cousins, 'Patient Mobility and National Health Systems' [2007] 34 LIEI 183, 193.

[1150] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 106 and see also P Cabral, 'The Internal Market and the Right to Cross Border Medical Care' (2004) 29 EL Rev 673, 683 and M Cousins, 'Patient Mobility and National Health Systems' [2007] 34 LIEI 183, 193.

have gained by obtaining low-priority treatment which her PCT might have refused to fund on an exceptionality basis.[1151]

5.5.3 CAM and the problem of an undefined healthcare benefit basket

The final problem giving rise to destabilisation is the lack of restriction of the ambit of the healthcare package of the NHS. Under the Regulation of the social coordination schemes,[1152] reimbursement need only be granted for costs of treatment considered a benefit under the legislation of the Member State of insurance (home state). From the ECJ's patient mobility case law it can also be concluded[1153] that patients do not have a right to be reimbursed for non-covered benefits under the Treaty provisions.[1154] Thus Member States are not obliged to pay for the costs of treatments or benefits that are not covered by their own legislation, and patients going to another EU Member State to receive treatment can only claim reimbursement of costs within the limits of the cover provided by the healthcare system in their home state.[1155]

Member States are entitled to establish limitative lists excluding certain medical treatments from reimbursement. As the ECJ held in *Geraets-Smits*, EU law 'cannot in principle have the effect of requiring from a Member State to extend the list of medical services paid for by its social insurance system'.[1156] However, a list of such

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[1151] See also chapter 4.
[1152] Article 20 of Regulation 883/2004/EC replacing Regulation 1408/71 EEC.
[1153] eg Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931; Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473 and Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509.
[1154] Article 56 TFEU replacing Article 49 EC; see generally AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003) 302; C Newdick, 'The European Court of Justice, Trans-National Healthcare, and Social Citizenship – Accidental Death of a Concept' (2009) Wisconsin Intl L J 844, 861–62.
[1155] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509, para 97.
[1156] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473, para 87.

non-covered benefits would have to be drawn up in accordance with objective, non-discriminatory criteria which are known in advance.[1157]

The problem therefore is to define what treatments are covered, whether included or excluded, as benefits under any particular health system. As Newdick argues, healthcare systems throughout Europe do not generally create lists of treatments for which funding is or is not available, as the creation of such lists is too fraught with difficulty.[1158] Not only would it be difficult to decide on the inclusion criteria but also on who should be charged with making these decisions and keeping the list up to date.[1159] Instead, some EU Member States entrust the task of defining the insurance package to health professionals by using open criteria,[1160] such as including treatment which is 'adequate and appropriate' or which is 'normal in the professional circles concerned'.[1161] In England, the generic words describing the duty of the Secretary of State for Health are to promote 'a comprehensive service'.[1162] Such terms are too vague to define the precise parameters of the healthcare menu available to the population of a Member State, thus making it difficult to state precisely which specific treatments are not part of the benefit package.

[1157] ibid, paras 115–116, confirmed in Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, paras 115–116.
[1158] C Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual rights by Corroding Social Solidarity' (2006) 43 CML Rev 1645, 1661; see also R Klein, 'Defining a Package of Healthcare Services the NHS is Responsible for – the Case Against'(1997) 314 BMJ 505, 508 where he argues that health authorities may also retreat from blanket exclusions of certain treatments because of pressure from the medical profession claiming that only its members are qualified to determine what patients need; cf C Ham and A Coulter, 'Explicit and Implicit Rationing: Taking Responsibility and Avoiding Blame for Health Care Choices' (2001) 6 J Health Serv Res Policy 163, 167 arguing in favour of more explicit rationing to increase public confidence in the legitimacy of decisions.
[1159] C Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual rights by Corroding Social Solidarity' (2006) 43 CML Rev 1645, 1661.
[1160] AP van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart 2003), 302.
[1161] As in Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473.
[1162] National Health Service Act 2006 s 1 and Health and Social Care Act 2012 s 1; see also discussion in C Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual rights by Corroding Social Solidarity' (2006) 43 CML Rev 1645, 1661.

There are no specific exclusions from the benefits package available under the NHS. Local health authorities, at present PCTs charged with commissioning health services for their local population, design purchasing plans which may designate certain treatments such as CAM as low-priority. However, not only do the policies of low-priority treatments vary in different PCTs, there are no blanket exclusions of treatments, as health authorities are obliged to exercise their discretion in exceptional cases.[1163] Bowden asserts that where a patient obtains such low-priority treatment abroad it will be very difficult to determine retrospectively whether such treatment would have been available from her PCT on an exceptional case basis and whether she should therefore have her costs reimbursed.[1164] Thus, as long as a treatment is not banned outright, a treatment that is potentially available as a low-priority treatment from a PCT is likely to constitute a benefit.[1165] The concession made by the ECJ to national authorities to determine the list of treatments available to their nationals, which may then be reimbursed when accessed across borders, will therefore, in Newdick's words, have limited effect.[1166] Since CAM treatments are not completely excluded from NHS cover, patients wishing to access such treatments across borders may claim reimbursement of their costs from the NHS and potential legal challenges may lead to further destabilisation of the healthcare system.

[1163] See chapter 4.

[1164] H Bowden, 'EU Cross-Border Health Care Proposals: Implications for the NHS' (2009) 15 Eurohealth 18, 18–19.

[1165] See also C Newdick, 'The European Court of Justice, Trans-National Healthcare, and Social Citizenship – Accidental Death of a Concept' (2009) Wisconsin Intl L J 844, 862 arguing that to establish a 'negative' or 'black' list of disapproved treatments would fetter the discretion of local health authorities to respond to exceptionality claims by patients; see also R Klein and others, 'Rationing in the NHS: the Dance of the Seven Veils – in reverse' (1995) 51 British Medical Bulletin 769, 774 where the authors suggest that not explicitly limiting the NHS menu has the additional advantage of not giving the impression by health authorities that treatment is being rationed for purely financial reasons.

[1166] C Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual rights by Corroding Social Solidarity' (2006) 43 CML Rev 1645, 1661.

5.6. The Patient Mobility Directive 2011 as response to legal uncertainty

The uncertainty created by the ECJ's patient mobility case law led to only contained national implementation in England [1167] with directions and guidance by the Department of Health to NHS commissioners regarding the authorisation and reimbursement arrangements for NHS patients seeking treatment under the cross-border rules.[1168] However, it had the consequence of extensive lobbying in Brussels by the Department of Health and NHS managers.[1169] The destabilisation threatening

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[1167] See eg E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 35 stating that only limited implementation in light of ECJ case law occurred at the level of the local NHS health authorities, probably due to the small numbers of recorded patients asking for reimbursement of treatment costs; see also S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' (2011) Journal of European Public Policy 220, 232 stating that NHS managers appear to respond to individual threats to use cross-border healthcare by encouraging the use of the pre-authorisation route or giving patients the treatment sought at home.

[1168] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 7 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 February 2012. In 2007, following the ECJ decision in *Watts*, the Department of Health published detailed guidance to local healthcare commissioners on handling requests for hospital care abroad, see Department of Health, 'Patient Mobility. Advice to Local Healthcare Commissioners on Handling Requests for Hospital Care in other European Countries following the ECJ's Judgment in the Watts case', London, 16 April 2007 <www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073850> accessed 23 August 2012. Regulations followed in 2010, with instructions to the NHS to reimburse patients who had obtained treatment abroad without prior authorisation, as long as the patients were eligible for the same treatment in England, and at the same price as the treatment would cost in England, see Department of Health, 'Cross-Border Healthcare and Patient Mobility: Revised Advice on Handling Requests from Patients for Treatment in Countries of the European Economic Area – Guidance for the NHS', 6 April 2010 <www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115256> accessed 20 August 2012; see also generally S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' (2011) Journal of European Public Policy 220.

[1169] See NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 2 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012. NHS lobbying started first on a small scale but was consolidated in 2007 with the opening of a European office in Brussels by the NHS Confederation with the aim to monitor and influence EU policy, see NHS European Office <www.nhsconfed.org/NationalAndInternational/NHSEuropeanOffice/Pages/Home.aspx> accessed 20 August 2012.

healthcare finances, policies and administrative procedures therefore led to significant engagement by the UK government and the NHS in EU politics.[1170]

It was to end the legal uncertainty and to reduce the possibility of legal challenge from patients which finally led to the adoption of the Patient Mobility Directive[1171] by EU Member States in January 2011 to be transposed into national legislation by October 2013.[1172] The aim of the Directive is *not* to encourage patients to receive treatment outside their Member State,[1173] but rather the Directive is expected to lead to clearer guidance for patients, administrators and healthcare professionals.[1174] To ensure that the rules under the Directive would not have a negative impact on the

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[1170] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' (2011) Journal of European Public Policy 220, 231 stating that while UK government influence was apparent in the Council, for example, with the contribution to the Council resolution on shared healthcare service values, the NHS also engaged significantly with EU policy-making.

[1171] Directive 2011/24/EU (Directive on the Application of Patients' Rights in Cross-Border Healthcare or 'Patient Mobility Directive').

[1172] The original proposed Article 23 in the Services Directive introduced under the auspices of Directorate General Internal Market and Services (DG Markt) codifying the law on free movement in healthcare was abandoned and health services were excluded completely from the Services Directive, see the history of the Services Directive in W Palm and I A Glinos, 'Enabling Patient Mobility in the EU; Between Free Movement and Coordination' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 521. As an initiative of DG SANCO concerned with social services, the Patient Mobility Directive addresses the obligations of the Member States concerning healthcare quality and safety standards, information, redress and liability, and protection of privacy of personal health data. In total, these obligations constitute a set of patients' rights although the Directive's main purpose is the setting up of a specific framework for cross-border healthcare; see generally W Gekiere and others, 'Free Movement of Services in the EU and Health Care' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 502; W Palm and I A Glinos, 'Enabling Patient Mobility in the EU; Between Free Movement and Coordination' in ibid 526; W Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' (2008) 39 <http://ssrn.com/abstract=1277110> accessed 5 May 2012.

[1173] W Gekiere and others, 'Free Movement of Services in the EU and Health Care' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 501.

[1174] W Palm and I A Glinos, 'Enabling Patient Mobility in the EU; Between Free Movement and Coordination' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 560; NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 2 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

NHS, the NHS European Office engaged with the lengthy decision-making process by extensive lobbying.[1175]

The new Directive, as a partial codification of the ECJ's case law, leaves intact the general principle that the basket of healthcare to which a citizen is entitled is the decision of the patient's home state,[1176] but that at the same time the free movement of persons within the internal market, non-discrimination, and necessity and proportionality of any restrictions on free movement, need to be respected.[1177] The Directive does not affect an EU citizen's rights to necessary healthcare during a temporary stay in another Member State, nor does it affect the healthcare services of employed or self-employed persons and their families moving within the Community. These continue to be covered by the Regulation on the coordination of social security schemes.[1178] Thus the Directive leaves the two parallel systems for healthcare provision across borders to a large extent intact. Patients are entitled to the more beneficial rights guaranteed by the EU regulations on the coordination of social security systems when the conditions are met.[1179] However, as no doubt a critical reference to the ECJ's judgments, it is made clear in the Preamble that the two cross-border systems of obtaining healthcare will now be coherent, with the effect that either the Directive applies or the EU Regulation on the coordination of social security schemes.[1180]

[1175] Department of Health, 'Cross-Border Healthcare and Patient Mobility: Revised Advice on Handling Requests from Patients for Treatment in Countries of the European Economic Area – Guidance for the NHS', 6 April 2010 <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115256> accessed 20 August 2012.

[1176] Patient Mobility Directive, Preamble 5. The legal basis of the Directive is Article 114 TFEU which states that Member States retain the full responsibility for healthcare, see Preamble of 7(4) of the Directive.

[1177] Patient Mobility Directive, Preamble (21) and Article 8(1).

[1178] Regulation 883/2004/EC; Patient Mobility Directive, Article 1(1) and Preamble (28); NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 2 <http://www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 February 2012.

[1179] Patient Mobility Directive, Preamble (31).

[1180] ibid, Preamble (30).

Although aiming to end legal uncertainty and to re-introduce stability it is debatable whether the Patient Mobility Directive achieves this as regards all cross-border healthcare. In the context of non-hospital-based or extramural treatment such as CAM, the new Directive appears to be perpetuating some of the existing legal uncertainties of the ECJ's patient mobility case law. The remainder of the chapter will consider the likelihood of further instability regarding the issues of prior authorisation, of the level of reimbursement with the difficulty of cost calculations, and of the undefined health benefit basket of the NHS.

5.6.1 The prior authorisation requirement regarding intra- and extramural treatment

The Directive allows Member States the option of introducing prior authorisation requirements for patients seeking cross-border healthcare.[1181] However, to justify prior authorisation by the home state, cross-border healthcare must be subject to planning requirements,[1182] and require either overnight hospital accommodation for at least one night[1183] or highly specialised or cost-intensive treatment.[1184] The Directive therefore codifies the ECJ's existing case law concerning the requirement for prior authorisation, but at the same time clarifies the definition of what constitutes hospital care, a term which had been left wide open by the ECJ.[1185] In keeping with the Directive being an initiative of the Directorate-General for Health and Consumer Protection (DG SANCO),[1186] prior authorisation of healthcare is also necessary where it might involve treatment presenting a particular risk to the

[1181] E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 34.
[1182] Patient Mobility Directive, Article 8(2)(a).
[1183] ibid, Article 8(a)(i).
[1184] ibid, Article 8(2)(a)(ii).
[1185] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509 [75] and AP van der Mei, 'Cross-Border Access to Medical Care: Non-hospital Care and Waiting Lists' (2004) 31 Legal Issues of Economic Integration 57, 62.
[1186] W Gekiere and others, 'Free Movement of Services in the EU and Health Care' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 501.

population,[1187] or where the healthcare provider raises concerns relating to the quality or safety of care, unless the healthcare provided is subject to EU legislation concerning a minimum level of safety and quality standards.[1188] No other cross-border healthcare cannot be made subject to the requirement of prior authorisation.[1189] As under the current case law, non-hospital-based CAM treatment will therefore not require prior authorisation as it is not subject to planning requirements and does not generally require highly specialised or cost-intensive medical equipment. There may be some uncertainty, however, regarding hospital-based CAM as in *Inizan*, or CAM treatment provided as part of a stay at a spa as in *Leichtle*.[1190] Would such treatment require authorisation as subject to planning requirements because the treatment was received in a hospital setting with overnight accommodation? It may of course be the case that providers, to avoid being caught by the Directive, will switch the treatment to an extramural setting with patients staying in hotel accommodation.

5.6.2 The level of the reimbursement and the issue of cost calculation

The Patient Mobility Directive confirms that the home state has to reimburse the costs incurred by an insured person[1191] who receives cross-border healthcare, as long as the healthcare in question is among the benefits provided by the Member State of insurance, or the patient's home state.[1192] Where the treatment is among the healthcare benefits, the home state must reimburse the patient the costs of the cross-border healthcare incurred, although it may also pay the costs directly to the host state.[1193] In the case of extramural care, where there is no prior authorisation, the patient will have to pay for the treatment first and then apply for reimbursement

[1187] Patient Mobility Directive, Article 8(2)(b).
[1188] ibid, Article 8(2)(c).
[1189] ibid, Article 7(8).
[1190] Although reimbursement of the costs of the accommodation at the spa is unlikely to be granted to an English patient cf *Inizan*.
[1191] Article 3(b) defines 'insured person' as a person who has a right to social security benefits in the competent Member State under Regulation 883/2004/EC, Article 1(c).
[1192] Patient Mobility Directive, Article 7(1).
[1193] ibid, Article 7(4).

from her home state. The Preamble states that patients must not be deprived of the more beneficial rights guaranteed by the social coordination route when the conditions are met.[1194] Where a patient is entitled to cross-border healthcare under both the Directive and the Regulation on the coordination of social security schemes[1195] and the application of the Regulation is more advantageous to the patient, the patient's attention should be drawn to this.[1196]

For the NHS patient who is treated with CAM in another Member State and is unlikely to have obtained prior authorisation, the possibility of parallel applicability of the two mechanisms is improbable.[1197] It is therefore the reimbursement mechanism under the Directive which applies. Furthermore, the Directive clarifies that under this reimbursement mechanism NHS commissioners are not required to pay more than the cost of the patient's treatment if it had been provided by the NHS.[1198] Unlike under the case law of the ECJ,[1199] patients no longer stand to benefit financially with reimbursement exceeding the actual costs of healthcare.[1200] However, in contrast to the case law of the ECJ,[1201] where the treatment costs in the host state are higher than the level of costs for the same treatment in the home state the patient will still lose out financially.[1202]

One of the major uncertainties concerning cross-border healthcare which continue to be relevant under the Directive is how domestic costs are determined.[1203] Following

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[1194] ibid Preamble (31).
[1195] Regulation 883/2004/EC.
[1196] Patient Mobility Directive, Preamble (31).
[1197] Regulation 883/2004/EC applies to the situation of undue delay in obtaining hospital treatment rationed by waiting lists in a Member State rather than to extramural treatment such as CAM.
[1198] Patient Mobility Directive, Article 7(4) ; see also E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 35.
[1199] Case C-368/98 *Abdon Vanbraekel and others v Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363, para 34 and Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403, para 21.
[1200] Patient Mobility Directive, Article 7(4).
[1201] See eg Case C-158/96 *Raymond Kohll v Union de caisses de maladie* [1998] ECR I-1931, para 42.
[1202] Patient Mobility Directive, Article 7(4).
[1203] E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 35.

ECJ case law, the Directive requires a transparent mechanism for the calculation of the reimbursable costs of cross-border healthcare to which a patient is entitled, which is to be based on objective, non-discriminatory criteria known in advance.[1204] Such a requirement will be difficult to fulfil where there is little existing cost information,[1205] at least not as regards non-hospital treatment such as CAM where there is likely to be more variation in the healthcare provided.[1206] As Sauter points out, there are likely to be immense difficulties associated with the introduction of sound cost accounting principles with a potential risk of significant litigation, and cross-subsidies and inefficiencies in the healthcare systems may become apparent.[1207] In any case, NHS tariffs may cover a package of care rather than just one procedure or treatment.[1208] Costs would therefore have to be broken down into the individual components where a patient receives a different package abroad, and lack of transparency may lead to potential challenges by patients.

5.6.3 The problem of defining the healthcare benefit basket of the NHS

Regarding the healthcare available to its citizens, the Directive confirms that it is for home states to decide, whether at local, regional or national level, to what healthcare benefits a patient is entitled, regardless of whether the patient is treated in her home state or across borders.[1209] The Preamble clarifies that patients are not entitled to

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[1204] Patient Mobility Directive, Article 7(6).

[1205] E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 35 stating that around 60% of NHS healthcare is not covered at present.

[1206] Hospital procedures are more likely to covered by a tariff; see also S Harvey and J Maybin, 'Patient Mobility in the European Union' (The Kings Fund London, 2010) 10 and see Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 143 where the ECJ held that, in a benefit-in-kind system such as that of the NHS, reimbursement under Article 49 has to be based on the objectively quantified costs of equivalent treatment in the NHS up to the actual costs incurred in the Member State of treatment (host state).

[1207] W Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' (2008) <http://ssrn.com/abstract=1277110> accessed 5 May 2012.

[1208] E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 35.

[1209] Patient Mobility Directive, Article 7(3); see also E Zanon, 'Health Care across Borders: Implications of the EU Directive on Cross-Border Health Care for the English NHS' (2011) Eurohealth 34, 35.

reimbursement of costs of healthcare provided in another Member State if such healthcare is not among the benefits provided in the home state.[1210] Patients have, however, the right to receive the benefits in another Member State which are also available in the home state.[1211] Where the treatment method is not specified precisely in the list of benefits,[1212] reimbursement should still be made available where the cross-border treatment corresponds to treatment provided for in the home state.[1213] There is no requirement for the NHS to pay for travel, accommodation and other expenses if those would not be covered were the treatment to be provided in England.[1214]

Several problems can be foreseen with regard to these provisions. Firstly, although reimbursement of a patient's costs related to her cross-border healthcare is optional, the Directive also declares that the home state may decide to reimburse other related costs such as accommodation and travel costs that would have been incurred if the patient had been treated in its territory, as long as these extra costs can be documented.[1215] The recital of the Preamble on this point suggests in addition that the Member State may reimburse such related costs even where these costs are not reimbursed in its own territory.[1216] It remains to be seen whether the interpretation of the meaning of *related costs* might lead to litigation, as the provision of the Directive could be said to prevent the functioning of the internal market and the free movement of goods, persons and services.[1217] In view of the decisions in *Watts*[1218]

[1210] Patient Mobility Directive, Preamble (33).
[1211] ibid, Preamble (34).
[1212] See Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403 and Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Zorgverzekeringen* [2001] ECR I-5473.
[1213] Patient Mobility Directive, Preamble (34).
[1214] ibid, Article 7(4).
[1215] ibid.
[1216] ibid, Preamble (34).
[1217] See ibid Article 7(11) and also Preamble (21) which exhorts Member States to respect the principles of free movement of persons within the internal market, non-discrimination and necessity and proportionality of any restrictions on free movement; see also the decisions in Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325 and in Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit* [2004] ECR I-2641.

and *Leichtle*,[1219] the provision appears to be a derogation of the rights established under Article 56 TFEU, which was held to cover ancillary costs such as travel where such costs would be covered in the home state.

Secondly, where a treatment method is not specified precisely in a Member State's healthcare package but the cross-border treatment corresponds to treatment provided for in the home state, the definitional problem of what constitutes the same or similar treatment could equally lead to legal uncertainty, as demonstrated by the case of *Inizan*.[1220] To include the same or similar treatments in the description of a healthcare benefit appears to contradict the principle that the patient can only obtain treatment which constitutes a defined benefit in her home state.[1221] Furthermore, it would place an additional requirement on the healthcare institution to list the treatment methods together with the treatments available under the healthcare system.

Thirdly, as the briefing report by the NHS European Office acknowledges, without a list of the types of healthcare covered or not covered there is a risk of legal challenge from patients trying to access treatments abroad which are not routinely available under the NHS.[1222] There are no lists of treatments which are completely excluded

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[1218] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para142.
[1219] Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit* [2004] ECR I-2641, para 41.
[1220] Case C-56/01 *Patrizia Inizan v Caisse primarie d'assurance maladie des Hauts-de-Seine* [2001] ECR I-12403; see also Case C-173/09 *Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa* [2011] 1 CMLR 29, para 67 where a Bulgarian national who suffered from a malignant disease of his right eye had proton therapy in Germany, an attachment of radioactive plates to the eye, rather than surgical removal of the eye ball, which was the only treatment available for his condition in Bulgaria. Reimbursement for the treatment in Bulgaria which had been refused by the relevant Bulgarian institution on the grounds that the treatment was not included in the benefits basket, had to be authorised because the list of medical benefits did not expressly and precisely specify the treatment methods included but only the types of treatment.
[1221] H Bowden, 'EU Cross-Border Health Care Proposals: Implications for the NHS' (2009) 15 Eurohealth 18, 19.
[1222] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 5 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

from cover, as the cases on exceptional circumstances have demonstrated.[1223] This would also apply to CAM classified as a low-priority treatment but not completely excluded from cover by many PCTs. In order to minimise uncertainty for commissioners and patients the NHS European Office considers it a key issue for the implementation of the EU rules that clear lists are established.[1224] Such lists would be drawn up locally by PCTs, and in future by CCGs, rather than nationally, with the NHS moving to a system of increasing local variation under the Health and Social Care Act 2012.

The Nuffield Trust, an independent organisation carrying out analysis of UK healthcare policy, has recently undertaken extensive research considering the advantages of defining a *national* package of healthcare benefits, concluding that developing such a package for the NHS is likely to be unworkable and its implementation may have adverse consequences.[1225] Some of the arguments against the national benefits package are equally applicable to a locally defined benefits package, which was also discounted by the Nuffield Trust. Thus, a local benefits package, whether inclusive or exclusive, would prove technically challenging to develop and enforce, might be inconsistent with promoting national strategic objectives such as cost-effectiveness and equity of access, could lead to a tendency to maintain historical patterns of use, give rise to variations in health funding decisions across the country, and would compromise the solidarity principle on which the NHS relies. 'In practice, benefits packages often lack the detail necessary to be more than a guide to local clinical practice…'[1226] With a positive list the contents of the package are explicit and all existing benefits would have to be reviewed, which would be a complex process. With a negative list, however, providers have to infer what the benefit package contains, with variations in benefits

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[1223] See discussion in chapter 4.
[1224] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 5 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.
[1225] B Rumbold and others, 'Is It Time To Set Out More Clearly What Is Funded by the NHS?: Rationing Health Care' (Nuffield Trust 2012) 6.
[1226] ibid 5.

provided being likely.[1227] There would be the additional problem of deciding which criteria to apply, beyond cost-effectiveness criteria,[1228] and how these criteria should be balanced against each other, in order to develop these lists. In addition, developing such a benefits package would involve considerable costs, especially as the positive or negative lists would have to be updated as new technologies or new evidence emerge.[1229]

5.6.4 Expected impact

Although future demand for cross-border care by UK patients is difficult to predict, the NHS European Office does not expect a large expansion of it.[1230] The current low usage of cross-border healthcare is based on the assumption that patients prefer to be treated as close to home as possible. This assumption, however, neglects the lack of information available to the public about cross-border healthcare rights. As the NHS European Office states, 'It will take time for the Directive to bed in, for the rules to be understood and the message to get out to the public'.[1231] For example, the Directive enables a patient to access private healthcare providers in another Member State and obtain reimbursement of the treatment costs by her home state, although she would not be entitled to the same in her home state if the private healthcare is not part of its social security system.[1232] As regards CAM, the Directive therefore permits the English patient access to a private or public CAM provider in another EU Member State with a right to reimbursement of the costs of treatment by the NHS. For the purposes of the Directive, a healthcare provider is any person or legal entity legally providing healthcare, including CAM, in another Member State which

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[1227] ibid 24.
[1228] Assessing cost-effectiveness will be very difficult in some treatment areas, see the discussion in chapter 4.
[1229] B Rumbold and others, 'Is It Time To Set Out More Clearly What Is Funded by the NHS?: Rationing Health Care' (Nuffield Trust 2012) 35.
[1230] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 5 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.
[1231] ibid 6.
[1232] Patient Mobility Directive, Article 1(4).

is not the patient's home state.[1233] Such a person or legal entity could be, for example, a medical practitioner who has moved from the patient's home state and set up practice in another EU Member State.[1234] It could also be any healthcare professional or a group of healthcare professionals who lawfully provide CAM treatment in another EU Member State.[1235] The Directive creates opportunities for healthcare providers to market their services to patients in other EU countries. As long as CAM is not excluded altogether from the NHS healthcare benefits basket, or from the local benefit basket of health authorities, CAM providers from the UK establishing themselves under the Treaty provisions in other Member States[1236] may market their services to NHS patients in the knowledge that the treatment costs will be reimbursed. The Patient Mobility Directive may therefore risk further destabilisation of the English NHS.

5.7. Conclusion

As has been described, litigation by patients claiming healthcare rights beyond borders has had a destabilising effect on the UK national healthcare system creating legal uncertainty, particularly due to the risk of patients obtaining low-priority treatments in another EU Member State to which they were not entitled at home. The restabilisation process set in motion by the ECJ's patient mobility case law led to the adoption of the patient mobility Directive, which will be transposed into national law by October 2013. Although the Directive is expected to end the legal uncertainty about the care patients can receive abroad, it has been argued that uncertainties remain. Further legal challenge is possible regarding the issues of prior authorisation and the definition of intra- and extramural treatment, the issues of the level of reimbursement and the calculation of the treatment costs and problem of the

[1233] ibid, Article 3 d(g).
[1234] Article 43 EC and general discussion in W Gekiere and others, 'Free Movement of Services in the EU and Health Care' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 470–93.
[1235] Patient Mobility Directive, Article 3 d(g).
[1236] Subject to the provisions of the Directive 2005/36/EC on the recognition of professional qualifications, and see also Case C-61/89 *Bouchoucha* [1990] ECR I-3551 and Case C-294/00 *Deutsche Paracelsus Schulen v Gräbner* [2002] ECR I-6515 concerning Member States' ability to regulate medical activities within their territory as they see fit.

undefined health benefit basket of the NHS under the Directive. Unless precise lists of included and excluded treatments are established by local NHS commissioners, as recommended by the NHS European Office,[1237] there is a risk of further instability. However, as has been concluded by the Nuffield Trust,[1238] a defined package of healthcare benefits is complex to develop and to keep up-to-date. Patients wishing to access CAM in another EU Member State may therefore claim reimbursement for a low-priority treatment from their health authorities, rekindling a process of destabilisation of the NHS.

[1237] NHS European Office, 'Patient Choice beyond Borders: Implications of the EU Directive on Cross-Border Healthcare for NHS Commissioners and Providers' (NHS Confederation, May 2011) 5 <www.nhsconfed.org/Documents/CrossBorderHealthcare_final_20110511_EZ.pdf> accessed 24 October 2012.

[1238] B Rumbold and others, 'Is It Time To Set Out More Clearly What Is Funded By The NHS?: Rationing Health Care' (Nuffield Trust 2012) 6.

Conclusion

As this research has suggested, there is considerable public demand for complementary alternative medicine (CAM) but very limited provision of it within the NHS. Complementary alternative therapy is challenged by many inside the medical profession for its lack of proven effectiveness and unproven safety record. At the same time a considerable number of GPs provide access to CAM, albeit CAM remains mainly privately funded. Despite these cost-disincentives, large numbers of people visit CAM practitioners for reasons that can only be surmised: discontent with biomedicine because of the side-effects of drugs and their lack of effectiveness in many chronic conditions, the belief that CAM is less invasive and more natural, the greater involvement by the patient in the treatment, and the different relationship between CAM practitioner and client.

This research is a contribution to the question of whether the current government policy of patient choice reconfigures a space for CAM as a treatment within the NHS. It has been argued that government policy of patient choice is leading to a potential opening for CAM within the NHS, with one of the drivers of the patient treatment choice policy clearly being the desire to please the public. Government rhetoric ranges from a reference to choice as liberal choice to choice as consumer choice, but at the micro- and meso-levels where these interpretations of choice are applied in practice, and where it matters most, little seems to have changed for the experience of patients. Private and public law litigation by patients wishing to enforce their choice of treatment at the micro- and meso-levels, apart from resolving the dispute in question, does, however, exert destabilising effects on institutions and practices. These effects are unlikely to be intended by the parties to the litigation. They do, however, support policy-makers with an overall destabilisation agenda. My conclusion is that policy-makers are not only encouraging patient choice at the micro-and meso-levels but are also using it as a policy mechanism or lever to achieve change within the NHS, to destabilise the incumbent institutions, leading to the possible emergence of a medical pluralism with other potential benefits. The concurrent theme in the government's healthcare policy of the responsibilisation of the patient fits with the emphasis of CAM on self-care and self-management, while

at the same time enabling policy-makers to claim support for the traditional values of the NHS.

The different interpretations of patient choice

My research has shown that choice carries different meanings in different contexts and that these different meanings are also employed by policy-makers in their political and policy discourse. The thesis explains that there are three discernible interpretations of patient choice; choice as a liberal value, choice as consumer choice related to market exchange or market principles, and patient choice as a policy mechanism. The interpretation of choice used at the micro- level is that of choice as a liberal value, whereas at the meso-level, which includes choice of cross-border healthcare, it is that of consumer choice.

Choice as a liberal value

The thesis has explained that at the micro-level patient choice is linked with the concept of the right or freedom to choose as a liberal value, also circumscribed by the concept of autonomy. The interpretation of choice is that of the liberal interpretation of autonomy limiting individuals' demands on society. It is based on rational choosing, offering more than sheer choice. This reasoned choice is not unrestricted; the freedom of the individual to choose is not absolute. It is this conception of autonomy that comes closest to the interpretation of autonomy employed by judges in refusal of treatment cases. However, my research has shown that, even in refusal cases, judges' interpretation of autonomy and therefore choice is inconsistent, and is often linked with a determination of capacity.

Similarly, the research has suggested that a claim for a specific treatment, if based on a liberal understanding of autonomy, would be linked with the right to self-determination but has never been interpreted as an obligation on doctors to satisfy that claim. The judicial conception of autonomy therefore rarely puts the patient in control. Rather than giving the patient the right to choose, the courts rely on the best interest test. The doctor owes a duty to her patient to administer such treatment as is in the patient's best interests, a duty generally determined by the *Bolam* test,

meaning that the doctor should provide treatment regarded as proper by a 'responsible body of medical opinion'. A doctor can legitimately decide that certain treatments are not in the best interest of a patient and need not be made available. It is the doctor who decides whether a treatment is clinically indicated. In common law, patient choice is therefore decided in terms of the doctor's duties rather than the patient's rights. As the research has argued, the inconsistent interpretation of autonomy in human rights law also does not give the patient a legal right to compel a doctor to act against her clinical judgment.

The situation of the patient at the micro-level is therefore in stark contrast to the choice rhetoric of policy-makers at the macro-level. While promising what appears to be a right to choose, policy-makers subject patient choice to the condition that treatment should be clinically 'appropriate'. Thus policy-makers, while promising choice to the public on the one hand, retract this promise with an acknowledgement of the medical profession's power in the healthcare arena and the continuing role of the doctor in implicit resource allocation decisions within the NHS.

In the same vein, as regards the right of the patient to be informed about treatment alternatives, the research has confirmed that English law has little concern for patients' interests in arriving at an autonomous treatment choice. While the law of trespass would protect the patient's right to autonomy, the English judiciary has taken a minimalist interpretation of information requirements necessary for *real consent*, ruling out medical trespass as a course of action as long as the patient has been informed in broad terms about the treatment. Instead it is necessary to look to the law of negligence and a possible breach of the doctor's duty to provide information to the patient. The courts have preferred to impose liability for lack of information in negligence rather than trespass. English judges, however, do not assess the adequacy of the information provided to the patient in accordance with a reasonable patient standard, which might go some way towards the recognition of the patient's right to choose. With regard to the disclosure of alternatives, a doctor's duty is further interpreted as only referring to treatments recognised by the medical profession and routinely available within the NHS. Additionally, the rigorous application of the causation principles, making it necessary for the claimant to show

physical injury in form of the risk materialising, means that patients are rarely successful in a claim for non-disclosure in negligence.

Whether because of the deference of judges to the medical profession or because the courts are not concerned with prioritising patient rights but with balancing them with policy-based considerations, attempting to stem the escalation of costs of medical negligence cases, the interpretation of choice at the micro-level works for the policy-makers at the macro-level. As Clarke and others point out, 'the politics of choice works through the capacity of the word "choice" to flicker between … meaning[s]'.[1239] While the courts resort to an inconsistent interpretation of choice as autonomy, policy-makers can claim to promote populist 'choice'.

'Consumer' choice

The research has also demonstrated that choice can be linked with the idea of the consumer in the market exchanging money for the desired goods or services. The interpretation of choice as consumer choice is relevant in the context of healthcare mimicking market principles, in private healthcare and also in the context of treatment across borders in the European Union. Equally, at the meso-level, where the patient, with the support of her GP, disputes the lack of availability of a CAM modality as a 'low-priority' treatment on exceptionality grounds from the health authority, the choice involved is not liberal choice as a conception of autonomy but can be interpreted as the choice of the quasi-consumer in the market-mimicking public healthcare system which is constrained by limited resources. As was explained, the current PCTs, intended as the main purchasers of healthcare services, were created by New Labour by keeping the quasi-market principles of the purchaser/provider split, originally introduced by the Conservative government as part of the internal market. Likewise, the introduction of the Clinical Commissioning Groups by the current coalition government follows a quasi-market ideology.

[1239] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 251.

As the research has suggested, where the patient's individual funding request to her PCT on the basis of exceptional circumstances is refused, she can apply for judicial review of the decision. The role of the court is to oversee the legitimacy, procedural propriety and reasonableness of the decision, rather than assessing the merits of the patient's claim. In reaching its decision the court reviews the exceptionality criteria applied by the PCT, which will turn on the consideration of the effectiveness of the requested CAM treatment. I have argued that if the PCT can demonstrate that it has considered the effectiveness of the CAM modality and also its cost-effectiveness, invalidation of its decision by the court is unlikely. The 'consumer choice' in this context is therefore largely dependent on the court's role in judicial review proceedings.

The research concludes that any refusal of this quasi-consumer choice at the meso-level is generally removed from the macro-level. The devolution of decision-making from central government to local health authorities has the advantage of avoiding the public perception that lack of patient choice is national policy. Blame lies with local administrators, whose decisions are subject to judicial review for their lawfulness and transparency. National policies of developing personal healthcare budgets are further evidence that any lack of consumer choice at the local level is not due to the local administration of national policies but of their own making. Also consistent with this analysis is the response by the current coalition government to the recommendations regarding the use of homeopathy in the NHS by the House of Commons Science and Technology Committee.[1240] Rather than accepting the recommendations of its own Chief Scientific Adviser to stop endorsing homeopathy on the NHS, decisions on the appropriateness and availability of homeopathy were left to be made at the micro- and meso-levels between doctor, PCT and patient. The overriding reason for the NHS provision of homeopathy was that homeopathy provides patient choice.

[1240] Department of Health, *Government Response to the Science and Technology Committee Report, 'Evidence Check 2: Homeopathy'* (HMSO 2010).

As the thesis has emphasised, consumer choice is the interpretation of the right of patients to receive healthcare in another EU Member State, and to be reimbursed by their healthcare system. This consumer right has been established in a series of judgments of the European Court of Justice which interpreted elective cross-border healthcare as an economic service within the meaning of the Treaty. The Court held in *Watts* that these rights of free movement to access cross-border healthcare and claim reimbursement of the cost of treatment from the 'home' Member State also apply to publicly funded healthcare systems such as the NHS.[1241] The UK government's argument that the NHS did not provide services for remuneration was rejected, despite the fact that the connection between medical services and the remuneration for these services is indirect. The right of consumers in the ECJ's mobility case law has extended to a right to access not only orthodox medicine but also CAM, which is generally not routinely funded in EU Member States.

Although the interpretation of choice as consumer choice in the EU market coincides with the government's enthusiasm for patient choice domestically, and EU cross-border mobility has clearly helped the consumer choice agenda,[1242] the UK government's support for the expansion of EU healthcare competency by the ECJ is not wholehearted. The creation and expansion of patients' rights to NHS-funded treatment in other EU countries caused legal uncertainty and instability in the English NHS originating from outside the UK. The lobbying in Brussels by the UK government to contain the wider ramifications of the patient mobility case law, resulting in the EU Directive on cross-border healthcare, is clearly evidence of governmental concern. However, as the thesis argues, policy-makers' promotion of patient choice within the English NHS needs to be viewed as part of the national political agenda of the government.

[1241] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325, para 90.

[1242] W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 4 <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012.

Choice as a policy mechanism

The meanings attributed to patient choice in policy documents and at the micro- and meso-levels of the healthcare service range from liberal choice to consumer choice. As the research has argued, the policy-makers' patient choice rhetoric may, however, also be open to different interpretations. Thus, patient choice has been interpreted and criticised as a proxy for competition, efficiency, marketisation and possible privatisation policies. The more recent policies of personalisation and responsibilisation have been similarly challenged since giving patients choice and making them responsible for their choices can be viewed as a technique to reduce costs while embedding a market-based model in the NHS.[1243] However, as the research has suggested, the management of costs through personalisation and the concurrent responsibilisation of patients within the NHS need not necessarily be a policy concentrated exclusively on the extension of a market model. After all, market mechanisms have not been the most efficient means to achieve cost savings in the NHS. Rather, as the research has pointed out, the policy of patient treatment choice, via its link with responsibilisation, has enabled policy-makers to claim a commitment to the traditional values of the NHS, in particular that of solidarity, whereas a commitment to the value of equity, although asserted by New Labour, may be more tenuous.

The research has argued that the policies of treatment choice, personalisation and responsibilisation, instead of being viewed as a coherent theme or narrative in developing a market model in healthcare, are employed by policy-makers as strategies with specific political objectives.[1244] The patient choice policies are used as a mechanism by government to encourage destabilisation of the institutions of the NHS considered resistant to change with the motivation which drives the choice

[1243] K Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England' (2010) 32 Law & Policy 313, 321.
[1244] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 251.

agenda including, amongst others, concern for cost containment, quality improvement, greater responsiveness and administrative modernisation.[1245]

The concept of destabilisation

The theme of destabilisation links the interpretation of choice at the micro- and meso-levels with the macro-level interpretation as a policy mechanism. The notion of destabilisation is borrowed from Sabel and Simon's concept of 'destabilisation rights'[1246] but, rather than referring to *rights*, destabilisation has been used as describing the possible, unintended ramification of threatened or actual litigation over treatment choice by patients at the micro- or meso-level. In contrast, at the macro-level, as has been argued, the destabilisation of the government's patient choice policy reflects a strategy aimed at system reform.

Destabilisation at the micro-level

The research has suggested that private law litigation or threatened litigation by patients against doctors, either in tort and human rights law for failure to provide the desired treatment or in negligence for their lack of informed choice, while rarely realising the desired choice, has other effects. Following Sabel and Simon, I have argued that the common law operates not only as a system of dispute resolution with precedential effects but has wider potential ramifications.[1247] Rather, as has been suggested, although patients rarely win informed consent cases or cases dealing with the demand for specific treatment by the patient, an action in common law is not a self-contained action between the immediate parties but has the effect of destabilising the status quo with an effect on healthcare practices and regulations. Taking the example of informed consent claims, destabilisation can be demonstrated by the frequent revisions of the medical practice guidance by the GMC reflecting a

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[1245] W Schelkle and others, 'Consumer Choice, Welfare Reform and Participation in Europe' (RECON, Online Working Paper 2010/26) 8 <www.reconproject.eu/main.php/RECON_wp_1026.pdf?fileitem=5456447> accessed 31 October 2012.

[1246] C Sabel and W Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1020.

[1247] ibid 1057.

higher standard of disclosure than that demanded by the law. Thus, as the research has concluded, even if informed consent cases have rarely resulted in an award of damages, litigation has provided a much-needed stimulus to greater debate about patients' informational needs. The destabilising effects of litigation seen at the micro-level are even more apparent in the case of public law litigation at the meso-level.

Destabilisation at the meso-level

The research demonstrates that the individual patient applying to a health authority to fund low-priority treatment on the basis of exceptionality is rarely successful. The definition of the exceptionality criteria emerging from judicial review case law is in very general and ambiguous terms,[1248] causing uncertainty for health authorities. However, as judicial review proceedings involve considerable expenditure by PCTs in terms of finances and staff time devoted to the case, it has been suggested that health authorities may concede an individual funding request, particularly where the treatment costs are not high, simply to avoid the expense of court proceedings[1249] and a negative outcome for the PCT, which would set a precedent leading to more potential claims.

As I have argued, where judicial review proceedings are brought against the health authority, litigation and adjudication have implications beyond the parties before the court, implications for health authorities generally and for potential future litigants. Judgments in public law cases, apart from being costly and time-consuming for a health authority and setting new precedents, have wider ramifications. The need for transparency by the health authority, the need to account for its rationing decision in public, and the media involvement in such cases opens the system to broader interests and voices. The research has suggested that the destabilising effect of public law litigation surpasses that of private law litigation. Following Sabel and Simon, public law litigation leads to public engagement, deliberation and

[1248] A Ford, 'The Concept of Exceptionality: A Legal Farce?' (2012) 20 Med L Rev 1, 26.
[1249] L Platt and others, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales' (2010) J Public Adm Res Theory (suppl 2): i243, i252.

negotiation[1250] and may lead to a restructuring of practices in the defendant and other institutions. This destabilising effect is likely to be further encouraged in view of the government's personalised healthcare agenda and the rolling out of personal healthcare budgets.

Similarly, as I have argued, legal uncertainties created by the patient mobility jurisprudence of the ECJ led to contained national implementation[1251] with directions and guidance by the Department of Health to NHS commissioners regarding the authorisation and reimbursement arrangements for NHS patients seeking treatment under the cross-border rules. To end legal uncertainty and to reduce the possibility of legal challenge from patients, the Patient Mobility Directive, a partial codification of the ECJ jurisprudence was adopted in January 2011 by the EU Member States to be transposed into national legislation by October 2013. Although EU patient mobility fits with the current government's domestic patient choice agenda, the need for restabilisation must be seen from the perspective of a government wishing to circumscribe patients' rights imposed by the expansive interpretation of the freedom of movement provisions of the TFEU by the ECJ. As has been suggested, while UK policy-makers may wish to employ patient choice as a mechanism for destabilisation *within* their own national healthcare system, the destabilising effects of the ECJ case law raised concerns about expanding EU competencies as well as about its anticipated negative effects on solidarity and equity within the English NHS.[1252]

Although the new Directive is expected to lead to clearer guidance for patients, administrators and healthcare professionals, the research has argued that uncertainties as to its likely impact remain, with possible legal challenges against local health authorities leading to further destabilisation at the meso-level. The main

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[1250] C Sabel and W Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds' (2003) 117 Harv L Rev 1016, 1017.
[1251] S Greer and S Rauscher, 'Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Healthcare Services Law' [2011] Journal of European Public Policy 220, 223.
[1252] C Newdick, 'The European Court of Justice, Trans-national Healthcare, and Social Citizenship – Accidental Death of a Concept' [2009] Wisconsin Intl L J 844.

obstacle for a patient wishing to access NHS-funded CAM in another EU Member State would be the existence of a clearly defined NHS benefit basket which excluded CAM altogether. However, as the research suggests, the establishment of precise national or local lists of included and excluded treatments to reduce the risk of legal challenge is doubtful. Such lists are not only complex to develop, even if based on cost-effectiveness criteria alone.[1253] More importantly, local lists would fetter the administrative discretion of NHS commissioners and conflict with the underlying values of the NHS, while national lists are anathema to the government's patient choice policy. An undefined healthcare benefit basket will, however, cause renewed, albeit more constrained, instability, and this may well be in line with current government initiatives.

Destabilisation as political intention of patient choice policy

In contrast with the destabilising effects of actual or potential legal challenge at the micro- and meso-levels, the research has suggested that destabilisation at the macro-level is a consequence of the government's patient (treatment) choice policy. Thus, as has been argued, patient treatment choice, personalised healthcare and personal health budgets can be interpreted as proxies for instability as a dynamic of system reform.[1254] The policy of the current coalition government of extending primary care provision to include 'any qualified provider' similarly leads to volatility. Commissioning services within the NHS such as CAM which are currently outside the scope of NHS provision, and commissioning services from providers not previously employed by the NHS, is likely to encourage reorganisation in the primary care sector. The provision of such services is clearly driven by consumer demand, but at the same time policy-makers' patient choice policy is useful as a strategy to encourage wider-ranging institutional change in the NHS.

[1253] B Rumbold and others, 'Is It Time To Set Out More Clearly What Is Funded By The NHS?: Rationing Health Care' (Nuffield Trust 2012) 5–6.
[1254] J Clarke and others, 'The Antagonisms of Choice: New Labour and the Reform of Public Services' (2008) Social Policy and Society 245, 250.

Destabilisation and the reconfiguration of a space for CAM within the NHS

As the research has suggested, destabilisation and volatility in the primary care sector, together with consumer demand, policies of personalised healthcare and the concurrent responsibilisation of the patient, might reconfigure the space for the main CAM modalities within the NHS. This is despite the challenges for patient choice and patient treatment choice at the micro- and meso-levels. The link between policies of patient (treatment) choice and personalisation of healthcare with responsibilisation, which also underlies CAM with its emphasis on self-management and self-care, fits with a reconfigured space for CAM. The depreciation of the claims to expertise by orthodox medical practitioners which has occurred in general practice,[1255] and the changing relations between complementary and orthodox medicine, which are becoming noticeable, go to underline the emergence of a medical pluralism in the NHS. More extensive incorporation of CAM in health service provision has of course also been aided by the change in the special relationship between the state and the medical profession since 1990, and the regulation of the professions of osteopaths and chiropractors by Acts of Parliament. The current restructuring of expertise in general practice may be a populist move, particularly regarding patients suffering from intractable chronic conditions not amenable to cure by conventional medicine. The greater incorporation of CAM in public health service provision may also aid the drive for fiscal austerity because of the potentially lower cost of CAM, the reduced need for medical personnel[1256] and the reduced dependency on the NHS by the 'responsibilised' consumer. Incorporation of CAM may also allow a reformulation of the meaning of the 'comprehensiveness' of the NHS. However, it is unlikely to placate the opponents of CAM whose concern is the unproven effectiveness and potential safety of these treatment modalities ignored by the government's choice agenda.

[1255] See generally J Le Fanu, *The Rise and Fall of Modern Medicine* (2nd ed Abacus 2011).
[1256] S Cant and U Sharma, *A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State* (UCL Press 1999) 143.

Although this research is concerned with the effect of government choice policy on the availability of CAM within the NHS, the research has wider implications. These extend beyond the case study of CAM and beyond the availability of treatments designated as low-priority by PCTs. The public increasingly demands choice in public services, not only choice in healthcare. References to choice by policy-makers are also not limited to the healthcare arena but cover other welfare services, and EU policy coordination supports this domestic choice agenda.

Further research

With the establishment of the new clinical commissioning groups in April 2013, there is a need to examine the actual impact of the expansion of the primary care sector to include new providers, and to investigate what extent this expansion will include CAM providers. It also remains to be seen whether patients will be able to access these new services directly or whether referral to other 'qualified' providers will be via the GP. The effect on patient treatment choice of the change from the current PCTs to CCGs is also not clear at present. Equally, the impact of the transposition of the Patient Mobility Directive into national law by October 2013 on the informational rights of patients regarding different treatment modalities nationally and in other EU countries will require further investigation. The effect of the Patient Mobility Directive on patient choice domestically remains to be seen, as patients may well be able to claim treatment domestically from the new CCGs rather than obtain cross-border treatment.

Appendix 1
Abbreviations and Acronyms

ANH	artificial nutrition and hydration
BMA	British Medical Association
BMI	body mass index
BMJ	British Medical Journal
CAM	complementary alternative medicine
CCG	Clinical Commissioning Group
DG SANCO	Directorate General for Health and Consumer Affairs
DG Markt	Directorate General Internal Market and Services
DHA	District Health Authority
DNR	Do Not Resuscitate
EBM	evidence-based medicine
ECHR	European Convention on Human Rights
ECJ	European Court of Justice
ECtHR	European Court of Human Rights
EDTA	ethylenediaminetetraacetic acid; a crystalline acid that acts as a strong chelating agent and forms a sodium salt used as an antidote for metal poisoning and as an anticoagulant.
EU	European Union
FDA	Food and Drug Administration
GMC	General Medical Council
GP	general practitioner
HB	haemoglobin
HER2-positive breast cancer	breast cancer that tests positive for a protein called human epidermal growth factor receptor 2, which promotes the growth of cancer cells
HRA	Human Rights Act
IFR	individual funding request
IVF	in-vitro fertilisation
JAMA	Journal of the American Medical Association
NEJM	New England Journal of Medicine
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
PCT	Primary Care Trust
QALY	quality-adjusted life year

RCT	randomised controlled trial
TAG	technology appraisal guidance
TFEU	Treaty on the Functioning of the European Union

Appendix 2
Table of Cases

Canada

Ferguson v Hamilton Civic Hospitals 1983 Carswell Ont 705, 40 O R (2d) 577, aff'd (1980) 50 O R (2d) 754

Haughian v Paine (1987) 37 DLR (4th) 624 (Sask CA)

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Seney v Crooks 1998 ABCA 316

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Glass v UK [2004] ECHR 102

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Pretty v United Kingdom (2002) 35 EHRR 1

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Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* [2006] ECR I-4325

Case C-173/09 *Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa* [2011] 1 CMLR 29

United Kingdom

Airedale NHS Trust v Bland [1993] AC 789

Al Hamwi v Johnston and Another [2005] All ER (D) 278

Associated Provincial Picture Houses v Wednesbury Corp [1948] 1 KB 223

B, Re (Adult: refusal of medical treatment) [2002] EWHC 429 (Fam)

Birch v University College London Hospital NHS Foundation Trust [2008] EWHC 2237 (QB)

Bolam v Friern Hospital Management Committee [1957] WLR 582

Bolitho v City and Hackney HA [1998] AC 232 (HL)

C, Re (Adult: Refusal of Treatment) [1994] 1 WLR 290

Chatterton v Gerson [1981] All ER 257

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R (Burke) v General Medical Council [2005] EWCA Civ 1003

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United States

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Cobbs v Grant 502 P 2d 1, Cal SC (1972)

Cross v Trapp 294 S E 2d 446 (1982)

Ketchup v Howard 543 S E 2d 371 (2000)

Macy v Blatchford 8 P 3d 204 (2000)

Moore v Baker 989 F 2d 1129 C A 11 (1993)

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Schiff v Prados 92 Cal App 4th 692 (2001)

Schloendorff v Society of New York Hospital 105 NE 92 N Y (1914)

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Appendix 3
Table of UK Legislation/Statutory Instruments

Chiropractors Act 1994

Health and Social Care Act 2012

Human Rights Act 1998

Medical Act 1858

Medical Act 1983

Mental Capacity Act 2005

National Health Service Act 2006

National Institute for Clinical Excellence (Establishment and Constitution) Order (SI 1999/220)

NHS (General Medical Services) Regulations (SI 1992/635)

Osteopaths Act 1993

Appendix 4
Table of European and International Materials

Constitution of the World Health Organization (as adopted by the International Health Conference, New York, 19–22 June 1946)

EC Directives

EC Directive 2005/36/EC (Recognition of Professional Qualifications)

EU Directive 2011/24/EU ('Patient Mobility Directive')

EC Regulations

Regulation 1408/71/EEC

Regulation 883/2004/EC

France

Social Security Code (France), L.332-3, L.766-1 and R.332-2

The Netherlands

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Treaties

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